Columbia University Human Subjects Protocol Data Sheet

General Information

Protocol:	AAAT1474(M00Y01)	**Protocol Status:**	Approved
Effective Date:	07/27/2020	**Expiration Date:**	07/07/2021
Originating Department Code:		PSY Psychiatry (754300X)	
Principal Investigator:		Hankerson, Sidney (sh2894)	
From what Columbia campus does this research originate:		Medical Center	
Title:	Church-Based Depression Screening		
Protocol Version #:		**Abbreviated Title:**	Depression Screening
Was this protocol previously assigned a number by an IRB:			No

Is the purpose of this submission to obtain a "Not Human Subjects Research" determination?

No

Attributes

Special review type: Check all that apply or check "None of the Above" box.

[ ]Review for 45 CFR 46.118 Determination (involvement of human subjects is anticipated but is not yet defined)

[ ]Funding review for Administrative IRB approval (such as for Center or Training Grants)

[x]None of the above

IRB of record information: Will a Columbia IRB be the IRB that is responsible for providing review, approval, and oversight for this study?

Yes

Select the most appropriate response:

Columbia will be the IRB of record for the study procedures conducted by Columbia researchers (Note: this response will apply to most submissions).

Is this research part of a multicenter study?

No

Please indicate if any of the following University resources are utilized:

[ ] Cancer Center Clinical Protocol Data Management Compliance Core (CPDM)

[ ] CTSA-Irving Institute Clinical Research Resource (CRR)

[ ] CTSA- Irving Institute Columbia Community Partnership for Health (CCPH)

[x] None of the above

Background

Abbreviated Submission:

The IRB has an abbreviated submission process for multicenter studies supported by industry or NIH cooperative groups (e.g., ACTG, HVTN, NCI oncology group studies, etc.), and other studies that have a complete stand-alone protocol. The process requires completion of all Rascal fields that provide information

regarding local implementation of the study. However, entering study information into all of the relevant Rascal fields is not required, as the Columbia IRBs will rely on the attached stand-alone (e.g., sponsor's) protocol for review of the overall objectives.
If you select the Abbreviated Submission checkbox and a section is not covered by the attached stand-alone protocol, you will need to go back and provide this information in your submission.

Study Purpose and Rationale:
Provide pertinent background description with references that are related to the need to conduct this study. If this is a clinical trial, the background should include both preclinical and clinical data. Be brief and to the point.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

Depression is a leading cause of disability costing U.S. taxpayers $210 billion annually.[1] Significant racial disparities in depression exist with African American (AA) adults more disabled from the disease, and less likely to receive treatment compared to Whites.[2,3] These disparities have been linked to socio-economic, cultural, and contextual factors governing under-detection and under-treatment of depression.[4] For example, although most depression screening and treatment occurs in primary care settings, **AAs are half as likely to be screened for depression in these settings compared to white adults.**[5,6] The current proposal seeks to test a novel "meet people where they are" engagement model for depression screening and treatment referral among AAs, and evaluate its effect on detection of depression and receipt of treatment. Churches are among the most trusted and influential institutions within AA communities.[7] AAs have the highest rates of church attendance among all racial/ethnic groups in the U.S., with over 60% attending church several times per month.[8] Approximately 72% of AAs with a serious personal problem, including depression, seek help in Black churches.[9] Indeed, in our prior work we found that 20% of adults in Black churches screened positive for depression using the Patient Health Questionnaire-9 (PHQ-9).[10] However, subjects with a positive depression screen (PHQ-910) universally declined treatment referral when offered by research coordinators.[11] Importantly, and relevant to the current study, a significant knowledge gap exists regarding effective strategies for linking church-based depression screening to engagement with clinical providers among AAs.[12] **Community Health Workers (CHWs)** are trusted, culturally concordant lay health personnel from the local community with significant social capital.[13] CHWs have proven effective at providing evidence-based screening and linkages to medical care for several chronic illnesses such as cancer and cardiovascular disease.[14] Although these conditions do not carry the same level of stigma as depression among AAs, we hypothesize that CHWs deployed for church-based depression screening can help overcome cognitive barriers and increase **treatment engagement** - defined as attending a depression-related clinical visit for which the subject reported receiving information, referral, counseling, or medication for depression.[15] This proposal builds on extensive experience with depression and church-based research by the study team at Columbia University. Dr. Williams (Co-PI) completed a NIH-funded Randomized Controlled Trial targeting care-seeking behaviors for acute stroke, which involved 312 Black and Hispanic adults from 13 churches (Williams et al., 2019, JAMA Neurology).[16] In a separate NIMH-funded study (K23-MH102540), Dr. Hankerson (Contact-PI) trained 263 AA church members in an evidence-based mental health literacy intervention.[17] Through intramural funding, Drs. Williams and Hankerson created an 8-week CHW training program for Black churches in Harlem, NY, which includes an evidence-based program called **Screening, Brief Intervention, and Referral to Treatment**

(SBIRT). The brief intervention in SBIRT is Motivational Interviewing (MI): an empirically tested, client-centered counseling approach.[18] The overarching aim of the current study is to expand the scope of these CHWs to include depression screening, brief intervention, and referral.

REFERENCES

1. Greenberg PE, Fournier AA, Sisitsky T, Pike CT, Kessler RC. The economic burden of adults with major depressive disorder in the United States (2005 and 2010). *J Clin Psychiatry.* 2015;76(2):155-162.2. Hankerson SH, Fenton MC, Geier TJ, Keyes KM, Weissman MM, Hasin DS. Racial differences in symptoms, comorbidity, and treatment for major depressive disorder among black and white adults. *J Natl Med Assoc.* 2011;103(7):576-584.3. Williams DR, Gonzalez HM, Neighbors H, et al. Prevalence and distribution of major depressive disorder in African Americans, Caribbean blacks, and non-Hispanic whites: results from the National Survey of American Life. *Arch Gen Psychiatry.* 2007;64(3):305-315.4. Hankerson SH, Suite D, Bailey RK. Treatment disparities among African American men with depression: implications for clinical practice. *J Health Care Poor Underserved.* 2015;26(1):21-34.5. Ayse Akincigil, Elizabeth B. Matthews. National Rates and Patterns of Depression Screening in Primary Care: Results From 2012 and 2013. *Psychiatric Services.* 2017;68(7):660-666.6. Gilbody S, Sheldon T, House A. Screening and case-finding instruments for depression: a meta-analysis. *CMAJ.* 2008;178(8):997-1003.7. Lincoln CE, Mamiya LH. *The Black Church in the African American Experience.* Durham and London: Duke University Press; 1990.8. Lukachko A, Myer I, Hankerson S. Religiosity and Mental Health Service Utilization Among African-Americans. *J Nerv Ment Dis.* 2015;203(8):578-582.9. Chatters LM, Taylor RJ, Woodward AT, Bohnert ASB, Peterson TL, Perron BE. Differences between African Americans and Non-Hispanic Whites Utilization of Clergy for Counseling with Serious Personal Problems. *Race Soc Probl.* 2017;9(2):139-149.10. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med.* 2001;16(9):606-613.11. Hankerson SH, Lee YA, Brawley DK, Braswell K, Wickramaratne PJ, Weissman MM. Screening for Depression in African-American Churches. *American journal of preventive medicine.* 2015;49(4):526-533.12. Williams L, Gorman R, Hankerson S. Implementing a mental health ministry committee in faith-based organizations: the promoting emotional wellness and spirituality program. *Social work in health care.* 2014;53(4):414-434.13. Wennerstrom A, Haywood C, Wallace M, et al. Creating Safe Spaces: A Community Health Worker-Academic Partnered Approach to Addressing Intimate Partner Violence. *Ethn Dis.* 2018;28(Suppl 2):317-324.14. Wennerstrom A, Johnson L, Gibson K, Batta SE, Springgate BF. Community health workers leading the charge on workforce development: lessons from New Orleans. *J Community Health.* 2014;39(6):1140-1149.15. Wells KB, Jones L, Chung B, et al. Community-partnered cluster-randomized comparative effectiveness trial of community engagement and planning or resources for services to address depression disparities. *J Gen Intern Med.* 2013;28(10):1268-1278.16. Ravenell J, Leighton-Herrmann E, Abel-Bey A, et al. Tailored approaches to stroke health education (TASHE): study protocol for a randomized controlled trial. *Trials.* 2015;16:176.17. Kitchener BA, Jorm AF. Mental Health First Aid: an international programme for early intervention. *Early Interv Psychiatry.* 2008;2(1):55-61.18. Ravenell J, Thompson H, Cole H, et al. A novel community-based study to address disparities in hypertension and colorectal cancer: a study protocol for a randomized control trial. *Trials.* 2013;14:287.19. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care.* 2012;50(3):217-226.

Study Design:

Describe the methodology that will be used in this study, covering such factors as retrospective vs. prospective data collection, interventional vs. non-interventional, randomized vs. non-randomized, observational, experimental, ethnography, etc.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

Using a Hybrid Type 1 Effectiveness-Implementation design,[19] we propose a 2-arm, mixed-methods Cluster-Randomized Controlled Trial within 30 Black churches our CHWs currently attend. Guided by the Consolidated Framework for Implementation Research (CFIR), we will assess key implementation variables related to depression screening uptake. We will also assess patient-level barriers and facilitators of help-seeking behaviors for depression. Data collection will be prospective. We will randomize 15 churches to the intervntion arm (SBIRT) and 15 churches to the control arm (Referral as Usual).

Statistical Procedures:

Provide sufficient details so that the adequacy of the statistical procedures can be evaluated including power calculations to justify the number of participants to be enrolled into the study. Definitions of subject terms such as enrolled and accrued as used for Rascal submissions can be found in the Subjects section.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

The design is a cluster randomized trial with randomization at the level of churches. There will be 30 churches, 15 randomized to the intervention (SBIRT) and 15 to the usual care arm (Referral As Usual). We will screen an average of 100 adults per church, yielding a pool of 3,000 respondents. Based on our pilot study we posit that 20% of church attendees will screen positive for depression, defined as PHQ-910. The primary outcome is treatment engagement for depression (clinical encounters). Secondary outcomes include the QIDS-SR, (mean=16.3, SD=4.0 estimated from a previous study in an ethnically diverse sample), the PROMIS Depression scale (mean=50, SD=10), PROMIS and the SF-12 measure of quality of life (QoL) (mean=50 and SD=10). Clinically meaningful change on the QIDS-SR has been estimated as about 5 points. For the PROMIS short-form measure, a minimally important difference has been reported as an effect size of 0.3 to 0.5 (about one third to one half standard deviation units). There will be three waves of data: baseline, 3- and 6-months. Power calculations are presented for the primary outcome.

Power is > 0.80 for detection of clinically meaningful effects of approximately 10% to 11% group differences in treatement engaement (Primary Outcome).

Please see the attached document **"Stattistacal Design and Power Calculations"** for more detailed description of statistical procedures.

Exempt and Expedited

Is the purpose of this submission to obtain an exemption determination, in accordance with 45CFR46.101(b):

No

Is the purpose of this submission to seek expedited review , as per the federal categories referenced in 45CFR46.110?

No

Funding

Is there any external funding or support that is applied for or awarded, or are you the recipient of a gift, for this project?

Yes

Award Type	Funding Source Name	Name of awarding agency	Status	Award # or Application Date	Federal/State/Local Government Direct or Subcontract	What is the award covering?	Rascal PT Number
Federal/State/Local Government	NIMH	INSERM-National Institute of Health and Medical Research	Awarded/Received	1R01MH121590-01A1	Direct Recipient: No Subcontract Sites	Entire Protocol	PT-AABP8814

Locations

Location Type	Facility Name	Domestic or International	Geographic Location	Local IRB Ethics Approval	Local Site Approval
Offsite	St. Paul Baptist Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	Crenshaw Christian Center	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	First Corinthian Baptist Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	St. John's Baptist Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	Salem United Methodist Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	Universal Baptist Church, Inc.	Domestic	Brooklyn, NY	No, approval is not required	No, approval is not required
Offsite	Bright Temple AME Church	Domestic	Bronx, NY	No, approval is not required	No, approval is not required
Offsite	Greater Centennial AME Zion Church	Domestic	Mount Vernon, NY	No, approval is not required	No, approval is not required
Offsite	Christ Church International	Domestic	Jamaica, NY	No, approval is not required	No, approval is not required
Offsite	Sacred Fellowship Ministries	Domestic	Brooklyn, NY	No, approval is not required	No, approval is not required
Offsite	Grace Congregational Church of Harlem United Church of Christ	Domestic	New York, NY	No, approval is not required	No, approval is not required

Location Type	Facility Name	Domestic or International	Geographic Location	Local IRB Ethics Approval	Local Site Approval
Offsite	Antioch Baptist Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	New Covenant Temple	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	Bayanihan Seventh-day Adventist Church	Domestic	Flushing, NY	No, approval is not required	No, approval is not required
Offsite	St. Matthew Roman Catholic Church	Domestic	Brooklyn, NY	No, approval is not required	No, approval is not required
Offsite	Fresh Oil's Ministries	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	Mother African Methodist Episcopal Zion Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	St. Luke AME Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	St. Augustine Presbyterian Church	Domestic	Bronx, NY	No, approval is not required	No, approval is not required
Offsite	Convent Avenue Baptist Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	Hosanna City of Refuge Church	Domestic	Rosedale, NY	No, approval is not required	No, approval is not required
Offsite	Yonkers Seventh-day Adventist Church	Domestic	Yonkers, NY	No, approval is not required	No, approval is not required
Offsite	Metropolitan Community Church of New York	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	Canaan Baptist Church of Christ	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	St. Mark The Evangelist Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	Corona Seventh-day Adventist Church	Domestic	Corona, NY	No, approval is not required	No, approval is not required
Offsite	Ephesus Seventh-Day Adventist Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Offsite	Saint Martin de Porres Parish Our Lady of Victory Church	Domestic	Brooklyn, NY	No, approval is not required	No, approval is not required
Offsite	Goodwill Baptist Church Inc.	Domestic	Brooklyn, NY	No, approval is not required	No, approval is not required
Offsite	Mount Olivet Baptist Church	Domestic	New York, NY	No, approval is not required	No, approval is not required
Columbia/CUMC	610 West 130 Street, New York, NY 10027				

Personnel

UNI/Phone	Name	Role	Department	Edit/View	Obtaining Informed Consent
sh2894 212-543-6148	Hankerson, Sidney	Principal Investigator	PSY Clinical Programs (754520X)	Edit	Y
	Roles and Experience: Dr. Hankerson is Assistant Professor of Clinical Psychiatry at Columbia University, Vagelos College of Physicians and Surgeons (VP&S), Co-Director of the Columbia University Wellness Center. He conducted the first-ever, church-based depression screening study with the PHQ-9 and has research expertise in health disparities, depression, and church-based interventions				
aj2786 [redacted]	Joshua, Amita	Coordinator	ZUC Health Screening Center (6810302)	Edit	Y
	Roles and Experience: Ms. Joshua is an alum of Columbia's Mailman School of Public Health. She has expertise with church-based interventions, qualitative data collection and analysis, and study management				
hlm9 212-342-1698	Moats, Harmon	Coordinator	ZUC Health Screening Center (6810302)	Edit	Y
	Roles and Experience: Mr. Moats has over 20 years of experience conducting research and service deliver in upper Manhattan. He currently serves as Project Director for Columbia's Community Health Worker Training Institute				
jat61 718-581-1132	Teresi, Jeanne	Investigator	MED General Medicine (751880X)	Edit	N
	Roles and Experience: Dr. Teresi has over 20 years experience as a data analyst for NIH-funded studies incluсding numerous studies that have been conducted in churches and other community-based settings				
jm4498 469-432-1559	Mallaiah, Janhavi	Coordinator	NEU Stroke Operations (7524402)	Edit	Y
	Roles and Experience: Dr. Mallaiah has worked as Project Coordinator for several of Dr. Williams' community-based studies and has vast experience working with the CHWs.				
mmw3 646-774-6427	Weissman, Myrna	Investigator	PSY Epidemiology (754410X)	View	N
	Roles and Experience: Dr. Weissman is the Diane Goldman Kemper Family Professor of Epidemiology (in Psychiatry) at Columbia University. She was Site Director of the landmark Epidemiological Catchment Area (ECA) study, which was the first NIH-funded, nationally representative epidemiologic survey of mental disorders in the United States. She has 30 years of experience conducting depression screening studies in community and clinical settings.				
ow11 212-342-0941	Williams, Olajide	Investigator	NEU Stroke Operations (7524402)	Edit	Y
	Roles and Experience: Dr. Williams is a Professor of Neurology, an implementation scientist, and a board-certified neurologist with extensive experience in delivery of community based behavioral interventions, including those delivered in Black churches, in New York City.				
rs3108 617-699-6557	Shelton, Rachel	Investigator	SMS Sociomedical Science (821500X)	Edit	N
	Roles and Experience: Dr. Shelton is Assistant Professor of Sociomedical Sciences has expertise in Lay Health Worker Sustainability Frameworks and has expertise evaluating the efforts of paraprofessionals in Black churches. She also has expertise in qualitative data collection and analysis, integrating qualitative and quantitative data (mixed methods), implementation science, community-based intervention research, and evaluating the effectiveness of CHWs.				

Training and COI
The PI must ensure that each individual that is added as personnel has met the training requirements for this study (http://www.cumc.columbia.edu/dept/irb/education/index.html). For help identifying which research compliance trainings you may be required to take, visit the Research Compliance Training Finder.

UNI	Name	COI	HIPAA	HSP (CITI)	Research with Minors (CITI)	FDA-Regulated Research (CITI)	S-I	CRC	Good Clinical Practice (GCP)	GCP - Third-party tracking	GCP Refresher	Genetic Research Consent
sh2894	Hankerson, Sidney	01/09/2020	02/05/2011	03/05/2020								
aj2786	Joshua, Amita	06/09/2020	09/30/2017	09/30/2017	01/24/2017			07/15/2020				
hlm9	Moats, Harmon	02/11/2020	06/15/2004	12/14/2018		12/14/2018		12/23/2010				
jat61	Teresi, Jeanne	03/03/2020	03/26/2015	07/17/2020								
jm4498	Mallaiah, Janhavi	06/11/2020	09/07/2016	06/18/2019	09/13/2016			07/14/2020				
mmw3	Weissman, Myrna	07/15/2020	11/28/2003	07/15/2020	06/18/2019							
ow11	Williams, Olajide	10/24/2019	06/23/2006	04/24/2018	01/13/2015	01/13/2015			12/10/2018			
rs3108	Shelton, Rachel	09/03/2019	05/28/2010	05/02/2019	06/01/2010	03/25/2011						

Departmental Approvers

Electronic Signature: Amita Joshua (6810302) - Coordinator — Date: 06/22/2020

Electronic Signature: Jeanne Teresi (751880X) - Investigator — Date: 06/23/2020

Electronic Signature: Harmon Moats (6810302) - Coordinator — Date: 06/23/2020

Electronic Signature: Rachel Shelton (821500X) - Investigator — Date: 06/22/2020

Electronic Signature: Sidney Hankerson (754520X) - Principal Investigator — Date: 07/22/2020

Electronic Signature: Myrna Weissman (754410X) - Investigator — Date: 06/22/2020

Electronic Signature: Janhavi Mallaiah (7524402) - Coordinator — Date: 06/22/2020

Electronic Signature: Olajide Williams (7524402) - Investigator — Date: 06/23/2020

Privacy & Data Security

Indicate the methods by which data/research records will be maintained or stored (select all that apply):

[x]Hardcopy (i.e., paper)

Describe where and how the data will be stored:

Data collected on paper assessments will be stored at Hebrew Home at Riverdale (HHAR) under the leadership of Dr. Teresi.

Data will be collected via a computer assisted personal interview (CAPI) program called The Survey System. Data are stored directly on the computer hard drive and are not transmitted via the internet. In addition, the internet connectivity is disabled from study computers.

Secure data transfer procedures: As has been done with several other projects, HHAR staff will download assessment data from the Columbia secure server through secure VPN connections. There is double layer of protection in order to access the data. First, staff must login to the University VPN, then login again to the Columbia file server. Passwords for login are updated every 6 months.

[x]Electronic

Where will the data be stored?

Y

[x]On a System

[x]On an Endpoint

Identify what type of endpoint will be used (select all that apply):

[x]Desktop Computer

[x]Laptop Computer

[ ]Mobile Device

[ ]Other

Does this study involve the receipt or collection of Sensitive Data?

Yes

If any Sensitive Data is lost or stolen as part of your research protocol, you must inform both the IRB and the appropriate IT Security Office (CUMC IT Security if at CUMC; CUIT if at any other University campus).

What type of Sensitive Data will be obtained or collected? Select all that apply:

[ ]Personally Identifiable Information (PII), including Social Security Numbers (SSN)

Will Social Security Numbers (SSNs) be collected for any purpose?

[x]Protected Health Information (PHI), including a Limited Data Set (LDS)

If any PHI is lost or stolen, you must inform both the IRB and the Office of HIPAA Compliance.

Indicate plans for secure storage of electronic sensitive data: check all that apply

[ ]Sensitive data will not be stored in electronic format

[ ]Sensitive data will be stored on a multi-user system

[x]Sensitive data will be stored on an encrypted endpoint

By Selecting an Endpoint Device and approving this protocol for submission to the IRB, the PI is attesting that the device and any removable media that may be used have been or will be registered and/or will be maintained in compliance with the University's Information Security Charter and all related policies. It is important that this information is updated, during the course of the study, as new devices are added.

Provide a description of how the confidentiality of study data will be ensured, addressing concerns or protections that specifically relate to the data storage elements identified above (e.g. hard copy, electronic, system, and/or endpoint):

Data will be collected in two ways: 1) paper assessments collected in person; 2) electronic assessments collected via Zoom will be collected via a computer assisted personal interview (CAPI) program called The Survey System.

To address confidentiality of paper assessments, hard copies of the completed assessments will be stored in a locked file at Hebrew Home at Riverdale for 10 years after study completion.

To address confidentiality of electronic assessments, data are stored directly on the computer hard drive and are not transmitted via the internet. In addition, the internet connectivity is disabled from study computers.

Secure data transfer procedures: As has been done with several other NIH projects, Dr. Teresi and her staff at Hebrew Home at Riverdale will download assessment data from the Columbia secure server through secure VPN connections. There is double layer of protection in order to access the data. First, they must login to the University VPN, then login again to the Columbia file server. Passwords for login are updated every 6 months. In addition, research personnel will be required to used password protected laptops/computers. Data will be stored on HIPAA complient, encrypted servers that are only accessible to IRB approved personnel.

Additional efforts to protect participant confidentiality to the extent permitted by law will be ensured by the following:
*Each study participant will receive a code number through which all study data will be linked. The code will only be known by research personnel.
*Participant names, code numbers, and study data will be kept in a single locked file, accessible only to key study personnel working on the study.
*Information stored on the computer will be coded numerically.
*All study data will be reported in tabular/group format while no individual data will be reported.
*Records will only be available to research staff, and the Federal, State, and Institutional regulatory personnel, who may review records as part of routine audits.
*Legal advocacy organizations that have the authority under state law can access confidential subject records, but cannot re-disclose this information without participant consent.

If your project is not NIH funded, has a Certificate of Confidentiality (CoC) been requested for this research?
No

Provide a description of the protections in place to safeguard participants' privacy while information is being collected:
Data collection will occur in two ways. IN PERSON data collection will take pleace onsite at a church study site (see grant letters of support). Participants will submit their completed Patient Health Questionnaire-9 (PHQ-9) and other study assessments to the Community Health Worker (CHW) in a private church space to protect the participants' privacy.

ELECTRONIC data collection will take place one-on-one between a CHW and community member. CHWs will request that participants complete the survey in a private area of their current location to protect privacy.

Procedures

Is this project a clinical trial?
Yes

Is this project a clinical trial that requires registration with www.clinicaltrials.gov?
Yes

Has this study been registered with www.clinicaltrials.gov?
No

Please note that this section should be updated when the registration number is received. At this time, please indicate who will be responsible for registering the study:

Sidney Hankerson

Is this project associated with, or an extension of, an existing Rascal protocol?

Yes

Existing Rascal protocol #:

AAAR0889

Do study procedures involve any of the following?

Analysis of existing data and/or prospective record review

No

Audio and/or video recording of research subjects

Yes

Behavioral Intervention?

Yes

Biological specimens (collection or use of)

No

Cancer-related research

No

Drugs or Biologics

No

Future use of data and/or specimens

No

Genetic research

No

Human embryos or human embryonic stem cells

No

Imaging procedures or radiation

No

Medical Devices

No

Surgical procedures that would not otherwise be conducted or are beyond standard of care

No

Will any of the following qualitative research methods be used?

Survey/interview/questionnaire

Yes

NOTE: You must attach a PDF version of the survey(s)/interview(s)/questionnaire(s) to this protocol prior to submission.

Systematic observation of public or group behavior

No

Program evaluation

No

Will any of the following tests or evaluations be used?

Cognitive testing

No

Educational testing

No

Non-invasive physical measurements

No

Taste testing

No

Is there an external protocol that describes ALL procedures in this study?

No

Please describe ALL study procedures in detail.

NOTE: Be sure to detail all of the procedures above to which a "yes" response was selected. Also detail any additional procedures that may or may not fall into the categories listed above.

Study procedures build upon the Columbia IRB protocol titled "Evaluation of a Community Health Worker Training Program" (#AAAR0889, Williams PI) and the New York State Psychiatric Institute IRB protocol titled "Church-Based Mental Health Assessment (#6368, Hankerson PI).

The Columbia University Community Health Worker (CHW) Program has trained and certified 102 CHWs from 42 Black churches in Harlem. These CHWs will serve as interventionists in the current protocol.

We will conduct a two-arm, cluster Randomized Controlled Trial in 30 Black churches that will compare the effectiveness of CHW-delivered Screening, Brief Intervention, and Referral to Treatment (SBIRT, n=15 churches) to Referral as Usual (RAU, n=15 churches) on treatment engagement (primary outcome). We will assess change in Mental Health-Related Quality of Life (QoL) and depressive symptoms at 3- and 6-months post-screening (secondary outcomes).

Prior to participant enrollment, CHWs will receive an additional 18 hours of booster training sessions prior to screening implementation. Training will take place at Columbia University's Wellness Center. We have added a training module on human subjects, including CITI and HIPAA certifications. The booster training curriculum will be reviewed by our Community Coalition for cultural appropriateness prior to implementation. Dr. Hankerson will facilitate each booster training session. Based on our experience with cultural and faith-based curriculum tailoring, our CHWs will not only be instructed on what to say, but also on what not to say, such as suggesting that depression or trauma was due to a person's moral failure. We have also included a module on trauma, informed by our pilot work, which revealed that a large proportion of adults in our target population have been exposed to some type of traumatic event. Guided by the information-motivation-behavioral skills (IMB) model, all CHWs will complete measures of knowledge (mental health literacy – Information), attitudes towards people with mental illness (Motivation), and self-efficacy (Skills) in providing services to people with mental illness prior to and after completion of the training. CHWs will also be observed for comfort and skill during booster sessions.

CHURCH-BASED STUDY PROCEDURES

Each CHW will collaborate with church leaders (see study sites and letters of support) to organize depression screening events at church health-focused programs. Two CHWs and at least one Project Coordinator (PC) will be present at the church for each screening event to assist with scoring the Patient Health Questionnaire-9 (PHQ-9), interpreting the results, and study enrollment. Eligibility for depression screening include: 1) Adults 18 years and older; and 2) English-speaking. There are no exclusion criteria for general depression screening. The screening will occur in a private space in the church to protect participant confidentiality. The screening survey will include the PHQ-9 and demographic information. Participants will submit their completed survey to the CHW in a private church space, who will quickly assess for suicidality by examining responses to Question #9 of the PHQ-9. Eligibility for the Randomized Controlled Trial (RCT) depends on the participants' total PHQ-9 score:

- Participants whose PHQ-9 9 (negative depression screen), are ineligible for the RCT and will receive a copy of Mental Health Resources.
- Participants whose PHQ-9 10 (positive depression screen), will be eligible for the RCT and invited to sign informed consent to participate in the study.

Safety Assessment and Quality Assurance. If a subject responds positively to Question #9 of the PHQ-9 or verbally endorses suicidality, the CHW will immediately initiate a safety assessment protocol. The CHW will assess and quantify safety risk with the Columbia-Suicide Severity Rating Scale (C-SSRS). After administering the C-SSRS, the CHW will immediately call the on-call study clinician (Drs. Hankerson or Williams or another licensed clinician). The on-call clinician will then conduct a brief, standardized clinical interview that reviews the score on the C-SSRS and quantifies the specific suicidal plans and access to lethal means (e.g., firearms). For participants with active suicidal ideation or behavior with imminent risk of harm to self or others, severe disability, or psychosis, the CHW will immediately collaborate with church staff and the participant's family for transfer to a local Emergency Room or Mobile Crisis. For participants with non-active suicidal ideation/behavior, the CHW will inform the study PIs within 24 hours and complete the Stanley-Brown Safety Plan94,95 (see 'Safety Plan' in Appendix). The CHW will inquire to see if the subject is currently in treatment, and if so, he/she will attempt to contact the participant's mental health provider. The subject will be referred for an in-person clinical interview with the on-call study clinician within 48 hours. If the subject does not attend or refuses the in-person assessment, Mobile Crisis will be dispatched to the residence.

Eligibility for Participation in RCT among Participants with a Positive Depression Screen. Inclusion criteria are: 1) Adults 18 years and older; 2) English speaking; 3) PHQ-910. Exclusion criteria are reporting active suicidality, or verbally endorsing homicidal ideation or psychotic symptoms, and those actively receiving formal treatment for depression or mental health illness (e.g. with medications and/or psychotherapy).

Intervention arm: [(Screening + Brief Intervention + Referral to Treatment), n=15 churches]. CHWs will provide two Motivational Interviewing (MI) sessions in each of the first three months, for a maximum of 6-MI sessions over 3 months (Table 1). The initial two sessions will be conducted in person at the church and follow-up sessions will occur either in-church or over the phone. Data will be collected on method of delivery. MI sessions will create a non-judgmental and supportive environment for eligible participants to move through the various stages of change associated with depression help-seeking. In the initial session, CHWs will focus on establishing rapport using open-ended questions, affirmations, reflections, and summary statements (OARS). They will then review depression symptoms based on the participants PHQ-9 score. The second session will focus on assessing motivation and confidence in seeking treatment and elicit barriers and facilitators for depression treatment. Follow-up sessions will involve summarizing the 'pros' and 'cons' of depression treatment; providing options for the participant based on the nature of barriers elicited from them; assessing participant's values and goals, to help them link their current mental health pattern to their goals; and summarizing what was discussed to clarify an action plan. The final component of SBIRT involves actual referrals to treatment. This begins with determination of the individual's health insurance status. Persons without insurance will be enrolled with the assistance of CHWs (who are certified New York State Insurance Navigators) into New York State health plans (insurance exchange or Medicaid). Based on our preliminary studies, we expect 12 to 15% of subjects to be uninsured. Individuals ineligible for health insurance will be referred to our network of free clinics providing mental health services. Uninsured individuals will also be referred to the NYC Dept. of Health Action Centers, to insurance information, and other social services (see Letters of Support). Referral involves the CHW calling (using study-issued prepaid calling cards) or offering to call the provider's office on behalf of the subject to make an appointment, plus a follow up appointment call reminder the day before the appointment.

Usual Care arm: [Referral as Usual (RAU), n=15 churches]. Distributing depression educational materials and contact information for treatment providers is the most common form of referral. This practice will represent "usual care" for our study. We will utilize depression educational brochures describing the nine hallmark symptoms of depression symptoms and the importance of seeking treatment: one from the National Institute of Mental Health (NIMH), one from the American Psychiatric Association (APA), and one from National Alliance of Mental Illness (NAMI). CHWs assigned to usual care churches will distribute the list of referral sites and pamphlets to study participants at designated screening events. No specific referrals will be made in this arm.

Assessments. Within two weeks of completing the PHQ-9 and study enrollment, Project Coordinators will conduct telephone baseline assessments with participants who signed informed consent. Table 3 shows the name and construct for each clinical measure collected at baseline, 3-months, and 6-months post screening.

VIRTUAL STUDY PROCEDURES
Considering COVID-19 and the New York State on Pause law, we will also conduct study procedures virtually. Study Project Coordinators will facilitate Columbia-HIPPA compliant Zoom screening events with church members from approved church study sites. The same study procedures outlined above will be followed, however, the interaction will be conducted via Zoom.

Recruitment And Consent

Recruitment:

Will you obtain information or biospecimens for purposes of screening or determining eligibility?

No

Describe how participants will be recruited:

This study involves three distinct study populations.

(1) Clergy (n=30): The lead pastor of each church study site will be recruited for participation in a semi-structured interview. The purpose of the interview is to explore clergy's perspectives of church-based depression screening and awareness of CHW activities in their church. Clergy will received a $100 gift card as compensation in the interview.

(2) Community Health Workers (n=60): CHWs form Columbia's Training Program will be eligible for participation in focus groups. The purpose of the focus groups is to identify barriers and facilitators of SBIRT (intervention) implementation and factors that would contribute to long-term sustainability of the intervention in churches. CHWs will receive $25 for participation in focus groups

(3) Community Members (n=600): Participants for the RCT will involve church members who screen positive for depression with the PHQ-9. CHWs will collaborate with church leaders to organize depression screening events at church health-focused programs. Additionally, funds will be provided for one screening event to take place as part of a Church Mental Health Forum. Two CHWs and at least one Project Coordinator (PC) will be present at the church for each screening event to assist with scoring the PHQ-9, interpreting the results, and study enrollment. We have successfully used mental health forums and health fairs to recruit participants in our church-based depression screening study and other church-based trials. Church members will also be recruited virtually via Zoom as described in the study procedures.

Select all methods by which participants will be recruited:

[ ] Study does not involve recruitment procedures
[ ] Person to Person
[ ] Radio

[ ] Newspapers
[ ] Direct Mail
[ ] Website
[x] Email
[ ] Television
[x] Telephone
[x] Flyer/Handout
[ ] Newsletter/Magazine/Journal
[ ] ResearchMatch
[ ] CUMC RecruitMe

Additional Study Information: Please add a description of your study as you would like it to be displayed on the RecruitMe website.

Informed Consent Process:

Informed Consent Process, Waiver or Exemption: Select all that apply

[x] Informed consent with written documentation will be obtained from the research participant or appropriate representative.

Documentation of informed consent is applicable to:
The study in its entirety

Identify the portion of the study (e.g., prospective portion, focus groups, substudy 2) or subject population for which documentation of consent will be obtained::

Documentation of participation will be obtained from::
[x] Adult participants
[ ] Parent/Guardian providing permission for a child's involvement
[ ] Legally Authorized Representatives (LARs)

Describe how participants' written consent will be obtained:
(1) Clergy (n=30): Project Coordinators and Research Assistants will review consent procedures with lead pastors and obtain consent at the church.

(2) Community Health Workers (n=60): Focus groups will occur at the Columbia University Wellness Center, where Drs. Hankerson and Williams are Co-Directors. Project Coordinators and Research Assistants will review consent procedures with the group

(3) Community Members (n=600): CHWs, Project Coordinators, and Research Assistants will be present at church study sites to obtain written consent from eligible adults who screen positive for depression (PHQ-9 greater than 10). Consent procedures will occur in a private area of the church to protect patient confidentiality

[ ] Informed consent will be obtained but a waiver of written documentation of consent (i.e., agreement to participate in the research without a signature on a consent document) is requested.

[x] A waiver of some or all elements of informed consent (45 CFR 46.116) is requested.

Waiver of consent is applicable to:

A portion of the study or subject population

Identify the portion of the study (e.g., retrospective chart review portion of the study) or subject population where a waiver of consent applies:

We request a waiver of consent for depression screening procedures with the PHQ-9

Select the applicable situation:

[x]This study qualifies for a waiver or alteration of consent as the following criteria are met in this study (provide justification for EACH of these criteria):

(1)The research involves no more than minimal risk to the subjects

Provide justification:

The PHQ-9 is a widely used, brief, self report measure that takes approximately 3 to 5 minutes to complete. We received waiver of consent on NYSPI IRB #6368 to conduct church-based depression screening with the PHQ-9.

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects

Provide justification:

The PHQ-9 is a screening measure and will not impact the welfare of subjects. If a patient expresses suicidal ideation on the PHQ-9, we will follow the Safety Procedures outlined in the previous section and initiate more in-depth assessment of suicidality with the Columbia-Suicide Severity Rating Scale

(3) The research could not practicably be carried out without the waiver or alteration

Provide justification:

It would be impractical and overly time consuming to try to obtain consent prior to screening with the PHQ-9. Only adults with a positive depression screen (PHQ-9 greater than 10), will be eligible for the RCT and will be required to provide informed consent to participate in the RCT

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation

Provide justification:

Church members will be informed of their PHQ-9 score and provided access to mental health referral resources regardless of whether or not they decide to enroll in the RCT>

(5) 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

****This waiver criterion does not apply if your research was initially approved before January 21, 2019, which is the general compliance date for the revised regulations at 45CFR46 subpart A.**

Provide justification:

N/A

[ ]This study qualifies for waiver or alteration of consent involving public benefit and service programs as the following criteria are met for this study (provide justification for EACH of these criteria):

[ ] Planned Emergency Research with an exception from informed consent as per 21 CFR 50.24.

[ ] This is exempt research.

Subject Language

Enrollment of non-English speaking subjects is not expected.

During the course of the study, if non-English speaking subjects are encountered, refer to the IRB's policy on the Enrollment of Non-English Speaking Subjects in Research for further details (http://www.cumc.columbia.edu/dept/irb/policies/documents/Nonenglishspeakingsubjects.Revised.FINALDRAFT.111909.website.doc

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Capacity to Provide Consent:

Do you anticipate using surrogate consent or is research being done in a population where capacity to consent may be questionable?

No

Research Aims & Abstracts

Research Question(s)/Hypothesis(es):

Aim 1: To compare the effect of SBIRT (Intervention arm) to Referral As Usual (RAU) (Usual Care arm) on treatment engagement. We will randomize 15 churches to each study arm. Adults with a positive depression screen (n=600) will receive either SBIRT (Screening + Brief Intervention + Referral to Treatment) or RAU (list of treatment sites + depression education pamphlets). We hypothesize that SBIRT will lead to increased treatment engagement (primary outcome) compared to RAU at 6-months post-screening. **Aim 2: To assess changes in mental health outcomes at 3- and 6-months post-screening.** We hypothesize that adults in the SBIRT arm will have better Mental Health-Related Quality of Life and fewer depressive symptoms (secondary outcomes) compared to those in the RAU arm.**Aim 3: To identify contextual factors that act as facilitators or barriers of depression screening and referral.** Guided by the Consolidated Framework for Implementation Research (CFIR), we will conduct a mixed-methods process evaluation with key stakeholders (clergy, CHWs, and congregants with positive PHQ-9 screen) to understand multi-level influences on depression screening and referral.

Scientific Abstract:

African American adults (AAs), compared to White adults, are half as likely to be screened for depression in primary care settings. Disparities in depression screening contribute to poor clinical outcomes, as AAs with depression are more disabled, sicker longer, and less likely to seek treatment compared to Whites. Black churches are trusted settings that provide “de facto” mental

health services for depression. Indeed, in the first study of its kind, the study team found that 20% of adults in Black churches screened positive for depression using the Patient Health Questionnaire-9 (PHQ-9). However, no subjects with a positive screen (PHQ-9 10) accepted a treatment referral when offered by research coordinators onsite for each screening. Community Health Workers (CHWs), who are trusted para-professionals from the target community, may bridge the gap between depression screening and treatment. We have trained and certified 102 CHWs from 42 Black churches in Harlem to deliver an evidence-based intervention called Screening, Brief Intervention, and Referral to Treatment (SBIRT), which is centered on culturally tailored Motivational Interviewing (MI). Thus, the scientific premise of this study is that employing CHWs to implement depression screening in Black churches will bridge the gap between church-based depression-screening and engagement with clinical providers. Using a Hybrid Type 1 Effectiveness-Implementation design, we propose a 2-arm, mixed-methods Cluster-Randomized Controlled Trial within 30 Black churches our CHWs currently attend. Based on our pilot data, we expect 20% of adults (n=600) to have a positive depression screen. Adults will be randomized based on church study site to either SBIRT (n=15 churches) or Referral As Usual (RAU, n=15 churches). We will then compare the effectiveness of SBIRT (Intervention arm) to RAU (Usual Care arm) on treatment engagement (primary outcome), defined as attending a depression-related clinical visit for which the subject reported receiving information, referral, counseling, or medication for depression (Aim 1). We will then compare changes in Mental Health Related Quality of Life and depressive symptoms (secondary outcomes) at 3- and 6-months post-screening (Aim 2). Finally, we will conduct a concurrent, mixed-methods (qualitative-quantitative) process evaluation to assess contextual facilitators and barriers of screening and referral (Aim 3). This study has potential for large-scale public health impact as 20 to 22 million Americans attend the 65,000 to 70,000 Black churches in the U.S.

Lay Abstract:

The overall aim of this study is to employ Community Health Workers (CHWs) to screen for depression in 30 Black churches and compare the effectiveness of Screening, Brief Intervention, and Referral to Treatment (SBIRT) (Intervention arm) to Referral As Usual (Control arm) on treatment engagement. We will assess patient-level outcomes (Mental-Health Related Quality of Life and depressive symptoms) at 3- and 6-months post-screening and conduct a mixed-methods process evaluation to assess multi-level facilitators and barriers of screening uptake. This research addresses the NIMH Division of Services and Intervention Research (DSIR) area of high priority to “employ strategic partnerships and community engagement / participation to enhance research capacity and infrastructure in underserved and diverse populations.”

Risks, Benefits & Monitoring

Abbreviated Submission:

The IRB has an abbreviated submission process for multicenter studies supported by industry or NIH cooperative groups (e.g., ACTG, HVTN, NCI oncology group studies, etc.), and other studies that have a complete stand-alone protocol. The process requires completion of all Rascal fields that provide information regarding local implementation of the study. However, entering study information into all of the relevant Rascal fields is not required, as the Columbia IRBs will rely on the attached stand-alone (e.g., sponsor's) protocol for review of the

overall objectives. .

If you select the Abbreviated Submission checkbox and a section is not covered by the attached stand-alone protocol, you will need to go back and provide this information in your submission.

Potential Risks:

Provide information regarding all risks to participants that are directly related to participation in this protocol, including any potential for a breach of confidentiality. Risks associated with any of the items described in the Procedures section of this submission should be outlined here if they are not captured in a stand-alone protocol. Risks of procedures that individuals would be exposed to regardless of whether they choose to participate in this research need not be detailed in this section, unless evaluation of those risks is the focus of this research. When applicable, the likelihood of certain risks should be explained and data on risks that have been encountered in past studies should be provided.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

We expect the level of risk due to this intervention to be minimal as no invasive measures or procedures are proposed. However, given the target sample, patients may experience distress as they are asked questions about depressive symptoms and other assessments. It is possible that some patients may find the frequency of calls and visits to be excessive. There is a potential risk to the participant with regards to possible violation of the participant's privacy since survey responses will be used as a source of data. Two CHWs and at least one Project Coordinator (PC) will be present for each depression screening event at designated church study sites. The CHWs will focus on reviewing PHQ-9 scores with community members. The PC(s) will focus on consenting eligible adults who screen positive for the Randomized Controlled Trial. When the prospective participant has completed the PHQ-9, the CHW and PC will briefly calculate their total PHQ-9 score and assess for suicidality. Individuals who score 10 on the PHQ-9 will be contacted within 14 days to schedule a baseline assessment and verify study eligibility. A telephone interview assessment will then be scheduled for those who agree. At the start of this interview, the interviewer will obtain informed consent from the patient. The consent will include permission to contact the participant’s treatment facility where they seek depression treatment, obtain selected data from the patients' other health care providers, and share information with our CUIMC collaborators. All participants will be informed that they can refuse to answer questions, stop the assessment at any time, or withdraw from the study if they so wish, without in any way affecting their eligibility or receipt of usual health or social services. Every effort will be made to streamline the interview and make it as comfortable as possible.Safety Assessment During Screening and Study Procedures. We have developed a comprehensive safety plan that will be activated if a research participant endorses suicidal ideation either verbally or on the PHQ-9 (included in IRB #6368). First, the CHW will screen for suicidality with the Columbia-Suicide Severity Rating Scale (C-SSRS). This measure to was designed to quantify the risk and intent of suicidal ideation / behavior. Second, the CHW will immediately contact the on-call clinician, who will conduct a standardized clinical assessment to evaluate immediacy of suicidal risk. If the research participant has *active* suicidal ideation/behavior, the on-call clinician will refer the participant to immediate clinical care by either calling 911 (if the patient consents for treatment) or Mobile Crisis (if the participant refuses to go to the emergency room). If the research participant does *not* have active suicidal ideation/behavior, the on-call clinician will refer the participant for an in-person clinical assessment with a licensed clinician on the research study team within 48 hours. If the participant

does show up or refuses the in-person clinical assessment, Dr. Hankerson will contact Mobile Crisis and have Mobile Crisis conduct a home safety assessment at the participant's home address.Protections Against Risk. The Multi-PIs will apply for a Certificate of Confidentiality. Confidentiality of patient information will be safeguarded in several ways. All research staff will be thoroughly trained in the need to maintain strict confidentiality. Data will be reported in aggregate form only. All participant-identifying information on paper will be kept in locked files accessible only to study staff. All electronic information will be password protected. No information obtained during the study will be used for any purpose other than the purpose for which the person has consented. The physical risks of the study procedures are minimal and the potential risks have been outlined above. The clinical care of any given participant will be handled entirely by the participant's primary care provider, unless emergency care is needed due to suicidality as outlined above, and study participants will be made aware of this at the baseline assessment. Similarly, any medical problem that arises during study visits will be referred to the participant's primary care provider. For those who do not have any provider, the PC will provide the participant with information to local health center.

Potential Benefits:

Provide information regarding any anticipated benefits of participating in this research. There should be a rational description of why such benefits are expected based on current knowledge. If there is unlikely to be direct benefit to participants/subjects, describe benefits to society. Please note that elements of participation such as compensation, access to medical care, receiving study results, etc. are not considered benefits of research participation.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

We expect that community members in both arms of the study will benefit from SBIRT or RAU. All study enrollees will receive a modest gift card compensation for participation:

1. Clergy will recieve a $100 gift card for completing semi-structured interviews.

2. Community Health Workers (CHWs) will receive a $25 gift card for completing focus groups. In addition, CHWs will receive an annual stipend that averages $500 each year for three years for conducting the depression screening activities described herein.

3. Community members with a positive depression screen will receive gift cards worth up to $65 for completing baseline, 3-, and 6-month assessments. In addition, a subset of community members will be randomly seleted to complete semi-structured interviews. Community members will receive a $25 gift card for completing semi-structed interviews.

Alternatives:

If this research involves an intervention that presents greater than minimal risk to participants, describe available alternative interventions and provide data to support their efficacy and/or availability. Note, participants always have the option not to participate in research.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

There are no alternatives to participation. Church members who decide not to participate or are ineligible for the RCT will be provided with mental health resources, if requested.

Data and Safety Monitoring:

Describe how data and safety will be monitored locally and, if this is a multi-center study, how data and safety will be monitored across sites as well.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

Data Safety Monitoring Plan. In compliance with NIH requirements, we will establish a data and safety monitoring plan (DSMP). The purpose of these plans is to ensure the safety of participants and the validity and integrity of the data. Considering the study rationale, population, procedures, and the risk: benefit profile as outlined; the overall risk level for participation in this screening intervention is classified as minimal. Due to the classification of this study as minimal risk, the following members of the investigative team will serve as the Data Safety Monitoring Committee and will perform the monitoring:Dr. Sidney Hankerson, Contact-Principal Investigator (Columbia University, Dept. of Psychiatry). Dr. Hankerson will be responsible for corresponding with NIMH. In addition to providing timely reports to NIMH, regarding (i) Unanticipated problems or unexpected serious adverse events that may be related to the study protocol, (ii) IRB-approved revisions to the study protocol that indicate a change in risk for participants, and (iii) Notice of any actions taken by the IRB or regulatory bodies regarding the research and any responses to those actions, Dr. Hankerson will be responsible for: Reviewing all PHQ-9 questionnaires and assessments by participants students at baseline, 3-, and 6-months; Reviewing safety plans documented by CHWs; and Reviewing rates of participant referral to treatment.Dr. Olajide Williams, Multiple-Principal Investigator (Columbia University, Dept. of Neurology). Dr Williams will provide site oversight by auditing CHW protocols and church sites where the intervention and control programs will take place. In addition to intervention fidelity monitoring, Dr. Williams will perform random interviews with CHWs (at least once at each church site) to evaluate the presence of any adverse reactions to the curriculum that may not be captured by questionnaire data. Dr. Jeanne Teresi, Co-Investigator (Hebrew Home at Riverdale). Dr Teresi is the head project statistician at the Research Division of the Hebrew Home at Riverdale. She and her team will act as the Data Coordinating Center (DCC) and regularly review program data, which will be discussed with the MPIs monthly. These data will include questionnaire items designed to capture adverse student emotional responses to the intervention. Dr. Teresi has directed over 100 DCCs for single and multi-site projects, and has served on many DSMBs.Project Director – TBN. The Project Director will be present on site at every intervention and control program. In addition to project management activities such as recruitment, consenting, training, and data collection, the PD will be responsible for identifying and reporting any adverse encounters - related or unrelated to the intervention – to the Multi-PIs. These include adverse emotional responses, interpersonal conflicts, physical accidents or any other participant safety concerns that may occur during the intervention.

Monitoring Study Safety:The data and safety monitoring plan will consist of reporting of adverse events to the IRB and to NIH trials. Adverse events will be reported to the Columbia IRB, which has the authority to halt the trial if it perceives that harm is occurring due to the intervention. Summaries of adverse events reports will be made to NIH in the yearly progress report and at the end of year 5, in the final report, unless the nature of a particular event is such that it bears reporting to NIH immediately. The progress of the trial will also be evaluated from the initial screening of participants by inclusion and exclusion criteria to the informed consent process to the provision of participant study instruction to staff training in Good Clinical Practices (GCP) and regulations pertaining to the Conduct of Human Participant Research. This will also include internal monthly quality control audits, periodic assessments of data quality and timeliness,

participant recruitment, accrual and retention, and protocol fidelity monitoring. One or more 'Early Safety/Trial Integrity Reviews' will be held during the early stage of protocol enrollment, to review early safety information, to review factors relating to quality of trial conduct, and to ensure proper implementation of procedures to reassess the sample size.

Subjects

Unless otherwise noted, the information entered in this section should reflect the number of subjects enrolled or accrued under the purview of Columbia researchers, whether at Columbia or elsewhere.

Target enrollment:

3,000

Number anticipated to be enrolled in the next approval period:

200

Does this study involve screening/assessment procedures to determine subject eligibility?

Yes

Target accrual:

600

Number anticipated to be accrued in the next approval period:

20

Is this a multi-center study?

No

Does this study have one or more components that apply to a subset of the overall study population (e.g. Phase 1/2, sub-studies)?

No

Target Enrollment Demographics:

Population Gender

Females	Males	Non Specific
60%	40%	0%

Population Age

0-7	8-17	18-65	>65	Non Specific
0%	0%	90%	10%	0%

Population Race

American Indian/Alaskan Native	Asian	Native Hawaiian or Other Pacific Islander	Black or African American	White	More than One Race	Non-Specific
0%	1%	0%	96%	3%	0%	0%

Population Ethnicity

Hispanic or Latino	Not Hispanic or Latino	Non-Specific
10%	90%	0%

Vulnerable Populations as per 45 CFR 46:

Will children/minors be enrolled

No

Will pregnant women/fetuses/neonates be targeted for enrollment?
No
Will prisoners be targeted for enrollment?
No
Other Vulnerable Populations:
[ ]Individuals lacking capacity to provide consent
[ ]CU/NYPH Employees/Residents/Fellows/Interns/Students
[x]Economically disadvantaged
[ ]Educationally disadvantaged
[ ]Non-English speaking
[ ]Other Vulnerable populations
[ ]None of the Populations listed above will be targeted for Enrollment
Subject Population Justification:
Women: We will recruit women and men equally. Based on our previous studies, along with prevalence estimates of depression and demographics of Black churches, we anticipate that rates of recruitment for the present studies will be approximately 3:2 female to male. In our preliminary depression screening study that involved three Black churches in New York City, 56% of participants were women and 44% of participants were men

Minorities: We are not excluding based on race or ethnic background. Because the long-term goal of this study is to reduce the racial disparities in depression and the study settings are historically Black churches, we expect the majority participants in this study to self-identify as Black or Hispanic. In our preliminary depression screening study that involved three Black churches in New York City, 96% self-identified as Black/African American.

Children: This study is only for adults ages 18 years and older
Does this study involve compensation or reimbursement to subjects?
Yes
Describe and justify reimbursement/compensation:
1. Clergy will recieve a $100 gift card for completing semi-structured interviews.

2. Community Health Workers (CHWs) will receive a $25 gift card for completing focus groups. In addition, CHWs will receive an annual stipend that averages $500 each year for three years for conducting the depression screening activities described herein.

3. Community members with a positive depression screen will receive gift cards worth up to $65 for completing baseline, 3-, and 6-month assessments. In addition, a subset of community members will be randomly seleted to complete semi-structured interviews. Community members will receive a $25 gift card for completing semi-structed interviews.

4. Each church study site will receive $1,000 for use of church space to conduct study procedures.
Are subjects eligible for compensation of $600 or more in a calendar year?
No

Attached Consent Forms

Number	Copied From	Form Type	Title	Active/InActive	Initiator
AABY9969		Consent	Commun ty Member	Act ve	S dney Hankerson

Number	Copied From	Form Type	Title	Active/InActive	Initiator
			Depress on Screen ng		(sh2894)

Documents

Archived	Document Identifier	Document Type	File Name	Active	Stamped	Date Attached	Created By
Yes	CHW Consent Form	Consent Form/Addendum	Consent Form CHW 6.17 .2020.pdf	Y	No	06/22/2020	S dney Hankerson (sh2894)
No	Consent Form CHW	Consent Form/Addendum	Consent Form CHW 7.17 .2020.pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
Yes	C ergy Consent Form	Consent Form/Addendum	Consent Form CLERGY 6.17.2020.pdf	Y	No	06/22/2020	S dney Hankerson (sh2894)
No	Consent Form CLERGY	Consent Form/Addendum	Consent Form CLERGY 7.17.2020.pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
Yes	Commun ty Member Consent Form	Consent Form/Addendum	Consent Form COMMUNI TY MEMBER 6.17.2 020.pdf	Y	No	06/22/2020	S dney Hankerson (sh2894)
No	Consent Form COMMUNI TY MEMBER	Consent Form/Addendum	Consent Form COMMUNI TY MEMBER 7.17.2 020.pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
No	CUIMC-IT Ema Ver f cat on	Ema /Commun c at on/Message	CUIMC-IT Ema Ver f cat on.pdf	Y	No	07/22/2020	S dney Hankerson (sh2894)
No	Grant App cat on	Fund ng/Grant App cat on/Subc ontract	F na Spec f c A ms and Research Strategy.pdf	Y	No	06/17/2020	S dney Hankerson (sh2894)
No	Am ta Joshua CU Cert f cate.TC009 8.aj2786.202007 15	Other	Am ta Joshua CU Cert f cate.TC009 8.aj2786.202007 15.pdf	Y	No	07/22/2020	S dney Hankerson (sh2894)
No	Church Study S tes Letters of Support	Other	F na Letters of Support.pdf	Y	No	06/17/2020	S dney Hankerson (sh2894)
No	Not ce of Grant Award	Other	Hankerson-W ams NIH N OA 1R01MH121 590-01A1.pdf	Y	No	06/17/2020	S dney Hankerson (sh2894)
No	Janhav Ma a ah CRC Tra n ng Cert f cate JM 7. 14.20	Other	Janhav Ma a ah CRC Tra n ng Cert f cate JM 7. 14.20.pdf	Y	No	07/22/2020	S dney Hankerson (sh2894)
No	Jeanne Teres CITI Comp et on Report 07.17.20 20	Other	Jeanne Teres CITI Comp et on Report 07.17.20 20.pdf	Y	No	07/22/2020	S dney Hankerson (sh2894)
No	MEMO Respons e to IRB Rev ew 07.22.20 20	Other	MEMO Respons e to IRB Rev ew 07.22.20 20.pdf	Y	No	07/22/2020	S dney Hankerson (sh2894)
No	Myrna We ssman CITI Comp et on Report 07.15.20 20	Other	Myrna We ssman CITI Comp et on Report 07.15.20 20.pdf	Y	No	07/22/2020	S dney Hankerson (sh2894)
No	Part c pant Recru tment Ema Scr pt	Recru tment Mater a	Part c pant Recru tment EM AIL Scr pt 6.17.2020.pdf	Y	No	06/26/2020	S dney Hankerson (sh2894)

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No	Soc a Support	Study Mater a /Instrume nt	8 Item Soc a Support Survey 07.2020. pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
No	CSSR-S	Study Mater a /Instrume nt	Br ef CSSRS-L fe ne-Vers on-2014.pdf	Y	Yes	07/22/2020	S dney Hankerson (sh2894)
No	Char son	Study Mater a /Instrume nt	Char son Comorb d ty Index 07.2020.p df	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
No	CPIC Hea th Serv ces	Study Mater a /Instrume nt	CPIC Hea th Serv ces 07.202 0.pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
No	Demograph cs	Study Mater a /Instrume nt	Demograph cs 0 7.2020.pdf	Y	No	07/20/2020	S dney Hankerson (sh2894)
No	Depress on St gma	Study Mater a /Instrume nt	Depress on St gma and L teracy 07.2020 .pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
No	CHW Interv ew Gu de	Study Mater a /Instrume nt	F na CFIR CHWs Interv ew 11.1.19.pdf	Y	Yes	06/17/2020	S dney Hankerson (sh2894)
No	Commun ty Member Interv ew Gu de	Study Mater a /Instrume nt	F na CFIR Subjects Screened 11.1.19.pdf	Y	Yes	06/17/2020	S dney Hankerson (sh2894)
Yes	CPIC Hea th Serv ces	Study Mater a /Instrume nt	F na CPIC Hea th Serv ces 11.1.19 .pdf	Y	No	06/17/2020	S dney Hankerson (sh2894)
Yes	MHP Appo ntment Ver fcat on Form	Study Mater a /Instrume nt	F na MHPAAV Form 11.2.19.pdf	Y	No	06/17/2020	S dney Hankerson (sh2894)
No	C ergy Interv ew Gu de	Study Mater a /Instrume nt	F na CFIR C ergy Interv ews 11.1.2019.pdf	Y	Yes	06/17/2020	S dney Hankerson (sh2894)
No	MHP Appo ntment Ver f cat on Form	Study Mater a /Instrume nt	MHPAAV Form 07.2020.pd f	Y	No	07/20/2020	S dney Hankerson (sh2894)
No	NYP Referra Gu de	Study Mater a /Instrume nt	NYP Menta H th D r UNSTAMPED 08.29.17.pdf	Y	No	06/17/2020	S dney Hankerson (sh2894)
No	PHQ9 V sua A d	Study Mater a /Instrume nt	PHQ9 V sua Answer A d ENGLISH.pdf	Y	Yes	06/17/2020	S dney Hankerson (sh2894)
No	PHQ9	Study Mater a /Instrume nt	PHQ9 07.2020.p df	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
No	PROMIS 8a Depress on	Study Mater a /Instrume nt	PROMIS SF v1. 0 - ED-Depress on 8a 0 7.2020.pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
No	PTSD 5	Study Mater a /Instrume nt	PTSD5-screen 07.2020. pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
No	QIDS 16	Study Mater a /Instrume nt	QIDS16-Se f Report Eng sh.pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
No	Re g ous H story	Study Mater a /Instrume nt	Re g ous and Sp r tua H story 07.2020. pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
No	Short Form 12	Study Mater a /Instrume nt	Short Form 12 07.2020.pdf	Y	Yes	07/20/2020	S dney Hankerson (sh2894)
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No	Stan ey-Brown Safety P an	Study Mater a /Instrume nt	Stan ey-Brown SAFETY PLAN 02.2019.p df	Y	Yes	06/17/2020	S dney Hankerson (sh2894)