**COVER PAGE**

**NCT06079853** Date of Protocol Approval: 10/18/2023

**Study Title:** The Use of Physiologic Measures and Sleep Health Promotion to Identify and Mitigate Predisposing Factors of Suicidal Ideation in Nurses

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**Sponsor: Columbia University School of Nursing**

**STUDY PROTOCOL**

The purpose of this study is to generate longitudinal pilot data that investigates 1) which factors (stressful life events, psychiatric characteristics, and work environment characteristics) are associated with stress and subsequent suicidal ideation; and 2) to explore the preliminary impact of an existing evidence-based sleep intervention, *Somni*[©14], on stress, psychological health, and suicidal ideation in working nursing professionals. The specific aims are:

**Aim 1. To investigate associations between sleep, stressful life events (life stressors, discrimination, lateral violence), psychiatric characteristics (psychiatric diagnosis, subjective mood), work environment characteristics (workload, shift type and duration, overtime, nurse work environment, and team relations) and stress (self-reported and heart rate variability) in working nursing professionals while controlling for standard covariates known to influence stress.** *Hypothesis 1:* Suboptimal work environment characteristics are positively associated with self-report and physiologic indicators of stress [heart rate variability (HRV)]. *Hypothesis 2:* Poor sleep (duration and quality) will be positively associated with self-report and physiologic indicators of stress (HRV).

**Aim 2. To determine if stress exposure (self-report and HRV) are associated with predisposing factors (sleep, stressful life events, additional psychiatric characteristics, and work environment characteristics), and to explore whether stress mediates the effect of predisposing factors on suicidal ideation in working nursing professionals.** *Hypothesis:* Nurses with low HRV are at higher risk for suicidal behavior when exposed to poor sleep, the presence of psychiatric characteristics (e.g. Depression), stressful life events, or suboptimal work environment characteristics (e.g., poor team relations).

**Exploratory Aim. To explore the preliminary impact of an existing sleep intervention (*Somni*©) on self-reported stress, HRV, sleep, and psychiatric health outcomes including depression, burnout, and suicidal ideation.**

**STUDY DESIGN.** This study is a prospective pragmatic pilot trial to generate data needed to inform a fully-powered longitudinal study consisting of nurses across a wider geographic region. There are 4 study components:

***1. Electronic Quantitative Surveys*** *(baseline, Week 4 & Week 8)* will consist of demographic questions and validated measures for personal characteristics, sleep, stressful life events, psychiatric characteristics, work environment factors, and all psychological health outcomes. **(Table 1).** The surveys will be administered 3 times (baseline, week 4 and week 8) to generate pilot longitudinal data.

***2. Psychological Assessment*** *(baseline).* To confirm a preexisting psychiatric diagnosis, a *Structured Clinical interview for DSM-5 Diagnosis* (Research version) (*SCID-5-RV)* will be administered in-person by a Psychiatric Mental Health Nurse Practitioner (PMHNP) at baseline. SCID-5-RV is a semi-structured interview guide for making major DSM-5 diagnoses such as mood disorders, psychotic symptoms, substance use, sleep, and trauma- or stressor-related disorders and takes approximately 45-60 minutes to administer. Studies suggest that prior history of mental illness, such as depression, has been linked to suicide.

***3. Physiologic Biomarkers*** (Weeks 1-8)**.** Heart rate and sleep (hours/day) will be collected using a wearable device, *Oura ring*©, a piece of jewelry that can be custom fit to each participant. Heart rate variability (HRV), a highly sensitive physiologic metric for stress, is the constant variation in milliseconds between beats, and controlled by the autonomic nervous system. Low HRV is a strong indicator of physiologic stress (fight or flight response) and has been associated with increased risk for suicide attempt. Studies have demonstrated high validity in the assessment of HRV and sleep using the *Oura ring*©. The device will also collect activity levels (steps/day) and sleep cycles, known confounders for stress levels.

**TABLE 1. Study Variables and Measures**

| Variable | Operational Definition | Measure |
|---|---|---|
| **Demographics** | Age, Sex, Gender, Race, Ethnicity, marital status, household income, parental status, smoking history, substance use; years of nursing experience | Validated single-items |
| **Sleep** | Sleep quality and duration | Pittsburgh Sleep Quality Index[44] ($\alpha = .83$)<br>*Oura ring*©<br>*Somni*© [14] |
| **Stress** | Self-reported stress<br><br>Heart Rate Variability | Perceived Stress Scale[45] ($\alpha = .76$)<br><br>*Oura ring*© |
| **Suicidal Ideation** | Suicidal Ideation | Columbia-Suicide Severity Rating Scale[46] ($\alpha = .94$) |
| **Stressful Life Events** | | |
| **Life Stressors** | 43-item checklist to assess changes in life (e.g. divorce; death of friend) | Holmes & Rahe Stress Scale[47] |
| **Discrimination** | Perceived discrimination | Perceived Discrimination Scale[48] ($\alpha = .93$) |
| **Lateral Violence** | Bullying/incivility | Negative Acts Questionnaire-Revised[49] ($\alpha = .90$) |
| **Psychiatric Characteristics** | | |
| **Psychiatric Diagnosis** | Psychiatric Diagnosis | SCID-5-RV (Research Version)[42] |
| **Subjective Mood** | Depression<br>Burnout | Beck's Depression Index-II[50] ($\alpha = .91$)<br>Maslach Burnout Inventory-HSS[51] ($\alpha = .91$) |
| **Work Environment Characteristics** | | |
| **Workload** | Perceived workload<br>Overtime<br>RN-patient staffing ratio | NASA Task Load Index[52] ($\alpha = .80$)<br>Self-reported number of hours<br>Standard ratio; frequency of shifts above standard |
| **Shift Work** | Shift type (day or night shift)<br>Shift duration (hours) | Validated single-items<br>Self-reported mean hours/shift<br>Number of quarterly overtime hours |
| **Practice Environment** | Nurse Participation; quality of care; management and leadership; human resources; nurse-physician relations | Practice Environment Scale-Nursing Work Index[7] ($\alpha = .80$) |
| **Team Relations** | Clinician team cohesiveness | Provider Co-management Index[27] ($\alpha = .96$) |

***4. Sleep Intervention*** *(Weeks 4-8) Somni*© is an evidence-based personalized sleep intervention aimed at promoting optimal sleep health and has demonstrated effectiveness in shift workers outside the healthcare sector (e.g. Disney). *Somni*© consists of a sleep kit and a smart phone application. The sleep kit is box of items with demonstrated past evidence of improving sleep health: Blue light blocking glasses, white noise machine, lavender spray, ear plugs, light blocking eye mask, and herbal tea. Rather than dictate a "one size fits all" approach to optimize sleep health, there is current evidence that individualized sleep interventions are recommended to optimize sleep quality. *Somni*© permits individualized sleep quality promotion and participants are able to select their preferred use, timing, and duration of each of the box contents. The kit is accompanied by a *Somni*© smartphone app that prompts participants to input the use of each component in the kit and provide a subjective sleep quality rating each day. Drs. Norful and Shechter have partnered with the developers of *Somni*© who will provide free sleep kits and app access to our study participants. The *Somni*© app is interoperable with the Oura Ring© and will automatically sync all physiologic and sleep data together in one location, fully accessible to the participants, and displayed in graphs in the *Somni*© app that are easy to read and interpret (e.g. total daily steps; daily sleep hours). *Somni*© will be implemented Weeks 4 through 8 to investigate its preliminary impact on stress and suicidal ideation by comparing survey and physiologic metrics from Weeks 1-4.

**STATISTICAL ANALYSIS**

First, we will calculate composite scores of individual measures (sleep, stressful life events, psychiatric characteristics, and work environment characteristics). Descriptive statistics will be calculated including means

and standard deviations (normally distributed values), median and interquartile range (non- normally distributed variables), or absolute and relative frequencies (categorical variables). Outliers and missing data will be assessed (outliers > 3 standard deviations from the mean will be removed). Significance level will be set at $\alpha$ = 0.05.

**Aim 1.** We will calculate bivariate Pearson or Spearman's rank order correlation coefficients as well as simple linear regression and univariate ANOVAs. We will use linear mixed models to examine the relationships between individual and composite scores of factors (sleep, stressful life events; psychiatric characteristics; work environment characteristics) and 1) self-report stress and 2) HRV, while controlling for personal characteristics (age, sex, highest degree earned, years of experience, years of practice in current environment, smoking status). We propose the following model to test all hypotheses:
$Y_g[E(\ _i)] = \beta_o + \beta_1 X_i + \beta_2 F$ where $Y_g$ represents the outcomes measure (self-report and HRV separately) for each participant i. $X_i$ are the individual-level covariates (e.g., sex, gender, race, age, mental health history), $F$ represents each job stressor and work environment variable. As the primary outcome is stress (mean score and mean HRV), possible distributions such as Poisson, zero-truncated Poisson, negative binomial, or zero-truncated negative binomial will be assessed to determine the best fit link function.

**Aim 2.** We will classify nurses into quartiles of high (top 25%), medium (middle 50%), and low (bottom 25%) HRV. We will use descriptive statistics to examine individual measures and composite scores of factors (sleep, stressful life events, psychiatric characteristics, work environment characteristics) and suicidal behavior [C-SSRS score]). To evaluate the change in suicidal ideation over time and the impact of each factor composite score, we will fit conditional latent growth curve models using 3 data points. The models will be expressed such that, given mean HRV and baseline composite scores for each factor category: $y_{it} = (\mu_a + \mu_\beta \lambda_t\ + \gamma_1 HCC_i\ + \gamma_2 WEC_i) + (\zeta_{ai} + \zeta_{\beta i}\lambda_t) + \varepsilon_{it}$ where $y_{it}$ is the C-SSRS score for nurse *i* at time *t*, $\mu_a$ is the latent variable for the intercept value (baseline score), $\mu_\beta$ is the random latent variable for slope (growth over time) for nurse *i* multiplied by the vector of factor loadings specifying time, $\lambda_{it}$, $\varepsilon_{it}$ is the time-specific residual for nurse *I*, $\zeta_{ai}$ and $\zeta_{\beta i}\lambda_t$ are random components of the latent intercept and slope variables, respectively. Sleep, stressful life events and psychiatric characteristics are fixed (time-invariant) predictors. The factor loadings for time on slope can be fixed to adjust for gaps in outcomes, which would allow for modeling more distant (e.g., 2025) data from baseline without increasing the number of timepoints included in the model. Further, we anticipate fluctuations in HRV over time. To accommodate the change in trend, we will explore both linear and quadratic growth functions. Baseline global sleep scores (PSQI), stressful life events, psychiatric and work environment characteristics will serve as predictors of suicidal ideation change over time. Individual nurse characteristics and psychiatric characteristic controls will be included as an interaction term to compare curves across nurses. To explore whether stress mediates the effect of predisposing factors on suicidal ideation, we will compare the models assessing the effect of predisposing factors on suicidal ideation with and without the mediator outlined by Barron and Kenny difference method which be used to gauge the size of the mediation effect.

**Aim 3.** We will calculate descriptive statistics, percentages, and frequencies for 1) each *Somni*© sleep kit component 2) subjective sleep quality via *Somni*© app 3) global sleep scores (PSQI score) and HRV. We will test differences in global sleep scores (PSQI), mean sleep duration (*Oura* ring), mean subjective sleep quality and use of sleep kit components at the individual level between the 3 data points. We will report the effect sizes and will test for significance in the model for each psychosocial and work environment factor, each *Somni*© sleep kit component (mean weekly frequency), and the mean PSQI score while controlling for age, sex, gender, race, and history of psychiatric diagnosis. We will repeat the same analysis modeling mean C-SSRS as the dependent variable. To evaluate the change in suicidal behavior over time and the impact of global sleep (PSQI score) and each *Somni*© sleep kit component (mean weekly frequency), we will fit conditional latent growth curve models.

# Columbia University Consent Form

## Protocol Information

**Attached to Protocol:** IRB-AAAU3204
**Principal Investigator:** Allison Norful (aan2139)
**IRB Protocol Title:** The use of physiologic measures and sleep health promotion to identify and mitigate predisposing factors of suicidal ideation in nurses: A pilot pragmatic trial

## General Information

**Consent Number:** CF-AACQ1190
**Participation Duration:** 8 weeks
**Anticipated Number of Subjects:** 25

**Research Purpose:** The overall purpose of this study is to identify factors (sleep, psychiatric characteristics, stressful life events, and work environment characteristics) that potentiate or mitigate adverse effects of real-world stressors that predispose nurses to suicidal risk, among other psychologic conditions.

## Contacts

| Contact | Title | Contact Information |
|---|---|---|
| Allison Norful | Principal Investigator | Phone: 212-305-7157<br>Cell: 516-477-9444<br>Email: aan2139@cumc.columbia.edu |

## Key Information

**This consent is being sought for research and participation is voluntary.**

**Study Summary:** We are currently recruiting participants for a study that aims to explore the associations between sleep, stressful life events, psychiatric characteristics (mood, depression, burnout), work environment factors (staffing ratios, leadership support, team relations**)** and physiologic stress that may precipitate or prevent suicidal risk. We also aim to test the impact of an evidence-based sleep health promotion intervention.

**Main Study Procedures & Duration:** Over the course of 8 weeks, you will be asked to complete the following:

1) **Electronic surveys at baseline, week 4 and week 8 (25-40 minutes each).** Survey consist of validated instruments to measure aspects of your personal and professional life. It will include mental health screening for depression, anxiety, and suicidal ideation/behavior.

2) **One-time Structured Clinical Interview for DSM-V disorders (45-60 minutes)** administered at baseline by a Psychiatric Mental health Nurse Practitioner. This semi-structured interview is used for diagnosing mood or psychotic disorders, substance use, sleep and trauma- or stress-related disorders.
3) **Measurement of Heartrate and sleep using a wearable jewelry device called the Oura ring.** The Oura ring is worn on your ring finger and using nanotechnology and sensors, can capture your activity level, heart rate, respiration, and sleep. You will be asked to wear the ring for 8 weeks.
4) **Sleep health promotion intervention.** During weeks 4-8 you will have the opportunity to use one or more sleep health promotion items including eye mask, white noise machine, aromatherapy lavender spray, blue blocking glasses, sun-blocking window shade, herbal tea and ear plugs**.** You will have the opportunity to select which item(s) you would like to use.

**Duration of participation**; 8 weeks

**Risks or discomforts to the prospective subject.** There may be mild skin irritation while wearing the Ouraring. The survey and/or structured clinical interview may elicit some emotional responses when inquiring about mood **or** psychological wellbeing.

**Benefit(s), if any;** There are no direct benefits. However, the sleep health promotion kit includes items that may improve sleep efficiency and effectiveness. You may keep the sleep health promotion kit at not cost to you.

**Alternative procedures:** This study is voluntary and as an alternative, you may choose not to participate. If you would like any information about free mental health resources, the study team will provide you with information at any time regardless of participation in this study.

## Information on Research

**INTRODUCTION**

Consent is being sought for research and participation is voluntary.

The purpose of this form is to give you information to help you decide if you want to take part in a research study.

This consent form includes information about:

- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have.

The principal investigator (the lead researcher for this project) [Dr. Allison A. Norful and/or Site Lead, Margaret Adler] will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

**The overall purpose of this study** is generate pilot data that investigates 1) which factors (stressful life events, psychiatric characteristics, and work environment characteristics) are associated with stress and subsequent suicidal ideation in working nursing professionals; and 2) to explore the preliminary impact of an existing evidence-based sleep health promotion kit intervention, called Somni©.

**Study procedures:**

a, Data collection will occur at baseline, week 4 and week 8. The total duration of study participation is 8 weeks.

b**. How many nurses are participating in this study?** We are current enrolling 25 nurses in this pilot study.

**c. What does participation entail?** Participation will include the following:

***Baseline***: Structured Clinical Interview- DSM-V (45-60 minutes); Baseline Electronic Survey (25-40 minutes); Start use of the OuraRing for 8 weeks.

***Week 4:*** Recurring Electronic Survey (25-40 minutes); Start to use the Sleep Health Promotion Kit.

***Week 8:*** Recurring Electronic Survey (25-40 minutes); Stop use of Oura Ring and Sleep Health Promotion. End of study participation.

d. **What is the Oura ring?** This publicly available device is a piece of jewelry (ring) worn on your ring finger. Using nanotechnology and sensors, the ring can capture your activity level, heart rate, respirations, and sleep. Your data is automatically uploaded to the Oura server for download by the study team. The ring should not be worn (and should be removed) during bathing, showering, or swimming. The ring will be provided to you for the duration of your enrollment in the study and needs to be returned to the study team when the study ends, you withdraw, or at the discretion of the study team. You will be asked to wear the Oura ring for all 8 weeks of study participation.

**e. What is the Somni© Sleep Health Promotion Kit?** This kit, publicly available and marketed by a company called Somni©, consists of multiple items that may improve the effectiveness and efficiency of sleep health. The contents of the kit include an eye mask, white noise machine, aromatherapy lavender spray, blue blocking glasses, sun-blocking window shade, herbal tea and ear plugs. You will be asked to use the sleep kit items (you may choose which to use and not to use) during week 4 through 8. You may keep the kit at no cost to you.

**f. What will the surveys ask?** The electronic surveys will be accessible to you on any electronic device with internet access. The survey consists of multiple instruments to capture aspects of your personal and professional life, including stressful life events, professional characteristics (perceived workload, nursing work environment, teamwork, burnout), stress levels, sleep quality and duration, and psychological wellbeing (screen for depressive mood, suicidal thoughts and/or behaviors).

**g. Who is eligible to participate?**

Eligibility criteria are: 1) currently practicing as a registered nurse in the clinical setting; 2) have worked continuously in the same position for at least 6 months; and 3) read, speak, and understand English language. Participants will be excluded if 1) >1-month sick leave in the past 3 months; 2) pregnancy (known physiologic stress confounder); and 3) other healthcare workers (e.g., physicians).

**h. Mental health resources:** We will provide a collective list of free and accessible mental health resources including but not limited to psychiatry referrals and consultations, confidential suicide and mental health toll-free hotlines, and

employee-based resources such as CopeColumbia. This list will be provided upon enrollment and then listed at the end of each survey. In addition, the study team will be able to provide this information to you via email at any time for the duration of the study.

## Risks

Are there any risks?

You may feel uncomfortable when answering some of the clinical interview questions or surveys that inquire about your past medical and psychiatric history, stressful life events, history of trauma, and work environment characteristics. You can choose to skip questions take a break when completing the sruvey if they make you uncomfortable, and return to complete it at a later time.A list of free mental health resources will be made available to you upon enrollment and also included at the end of each of the electronic surveys. In addition, the study team will be available to you if you need assistance with finding or navigating these resources.

Participation involves wearing a piece of jewelry (Oura Ring) for 8 weeks and may cause minor discomfort or the potential for skin irritation at the site. You may discontinue use at any time and notify the research team.

The components of the sleep health promotion box consist of interventions such as a light blocking glasses, sleep mask and lavender spray that may cause minor skin irritation. You will also receive an herbal tea. All allergies must be reported to the study at the start of the study. The use of any components of the sleep promotion box are voluntary. You may keep this box at the completion of the study.

Loss of confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the Privacy section of this consent form.

## Benefits

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

You may or may not receive personal (direct) benefit from taking part in this study. The possible benefits of taking part in this study include sleep health promotion through the use of the Somni Sleep Kit components that have previous evidence supporting their use.

You will not receive personal (direct) benefit from taking part in the electronic surveys or collection of your physiologic data through the OuraRing. However, the information collected from this research may help others in the future as we aim to understand what factors put nurses at higher risk for poor psychological health outcomes.

## Alternative Procedures

**WHAT OTHER OPTIONS ARE THERE?**

You may choose not to take part in this research study. Your decision to participate or not participate will in no way impact your employment.

## Confidentiality

**WHAT ABOUT CONFIDENTIALITY?**

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

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems such as a stolen computer may occur, although it is highly unlikely.

If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we

may collect and use for this research may include medical information that may be considered sensitive, including mental health screening for depression, anxiety, and suicidal ideation and/or behavior.

Any research information that is shared with people outside of Columbia University Medical Center and NewYork-Presbyterian Hospital will not include your name, address, telephone number or any other direct identifiers unless disclosure of the information is required by law or you have authorized the disclosure.

**Your safety is our priority.** In the event that you exhibit or screen positive for active health risk and immediate intervention is required (e.g., active suicidal behavior), we will break confidentiality and contact your health provider, family or designated emergency contact, and/or call 911 to assist you with seeking a higher level of care. A copy of mental health resources will be provided to you at time of enrollment, in the form of a pocket guide, and located at the end of each survey. Should you require assistance with any mental health referrals at any time throughout the study, you may contact any study personnel for more information.

Your survey responses, health information, and OuraRing data will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in an encrypted data file, a password-protected computer and only the investigator and authorized study staff will have access to the file.

The following individuals and/or agencies will be able to look at, copy, use, and share your research information:
- The investigator, study staff and other medical professionals who may be evaluating the study
- Authorities from Columbia University or NewYork-Presbyterian Hospital including the Institutional Review Board ('IRB')
- The Federal Office of Human Research Protections ('OHRP') and/or the Federal Drug Administration ('FDA')
- The sponsor of this study, [Columbia University School of Nursing], including persons or organizations working with or owned by the sponsor
- Data and Participant Safety Monitoring Committee
-OuraRing representatives assisting with the acquisition of biologic data collected by the device (coded data only).

The data collected by the OuraRing (heart rate, sleep patterns, activity levels) will not have any personal identifiers on the server to protect your privacy. Your data will be housed on the OuraRing server until the PI downloads all of your

data at the end of the study period for group analysis. Upon completion of your participation, your OuraRing will be deactivated and will not hold any of your personal data. The data downloaded from the study will be stored on a password protected, encrypted network drive at Columbia University, and only accessible to authorized study team members.

Your authorization to use and share the information collected for this research purpose does not have an expiration (ending) date. Once your research information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure.

Also, even if you revoke (take back) this consent and authorization, the researchers and the sponsor (if applicable) may continue to use and disclose the information they have already collected.

**WHAT ABOUT FUTURE USE?**

Identifiers might be removed from the identifiable private information or identifiable biospecimens and, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

Your authorization for the PI study team to use and share your de-identified health information or survey responses does not have an expiration (ending) date. In the future, your de-identified responses to the study and physiologic data (heart rate, activity levels or sleep patterns) may be combined with data from future groups of participants in larger studies to continue investigating the same study purpose.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Allison Norful (212-305-7157/ aan2139@cumc.columbia.edu) OR Co-Investigator, Margaret Adler (mma9026@nyp.org).

However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected.

## Compensation

**Will I get paid or be given anything to take part in this study?**

You will be compensated up to $100 for participation in this study. Incremental gift cards will be distributed upon completion of each study phase indicated below:

Baseline visit including SCID-V interview and baseline survey: $25 gift card

4-week data point (including OuraRing use and survey): $25 gift card

8-week datapoint (incuding OuraRing use and survey): $50 gift card

## Additional Costs

There are no costs to you for taking part in this study.

Taking part in this study will not involve additional costs to you. All devices, surveys, or materials (sleep health promotion kits) will be given free of charge by the sponsor company and study team. You and/or your insurance company will have to pay for any costs that are part of your regular medical care, emergency or urgent care, psychiatric wellness visits not offered by the free mental health resources provided through your employment.

## Voluntary Participation

**DO I HAVE TO BE IN THE STUDY?**

Taking part in this study is your choice. You may refuse to take part in the study or withdraw from the study at any time without jeopardizing your employment, or any other rights. The investigator may withdraw you at his/her discretion in the event that you are not completing the study procedures detailed in this form.

## Additional Information

**What if you have questions?**

You may ask questions at any time. You can ask now or later. You may talk to the researcher or someone else. If you have any questions about this study you can call or email

Allison Norful (Principal investigator)
telephone #212-305-7157
email: aan2139@cumc.columbia.edu

Margaret Adler (Co-Investigator)
telephone #914-734-3778
email: mma9026@nyp.org.

If you have any questions about your rights when you are in a research study, you may contact the Institutional Review Board by mail, telephone, or email at:

Human Research Protection Office
Institutional Review Board
Columbia University
154 Haven Avenue, 2nd Floor
New York, NY 10032
Telephone: (212) 305-5883
Email: irboffice@columbia.edu

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research. More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

## Statement of Consent

**Statement of Consent**

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

## Signatures

**Participant Signature Lines**

**Study Subject**

Print Name_____Signature_____

Date _____

**Research Signature Lines**

**Person Obtaining Consent**

Print Name_____Signature_____

Date _____