Date: Friday, November 05, 2021 2:21:55 PM
View: 01-00 Study Information

Print Close

1.0 Study Information:

1.1 * **Short Title:** Pulmonary rehabilitation and sleep quality

The Short Title Should be the sponsor protocol number. If there is no sponsor protocol, then enter 3-5 words or numbers that capture the important study characteristics and help identify the study.

1.2 * **Full Title of Research Project:**
Pulmonary Rehabilitation and its Impact on Sleep Quality; A Prospective Analysis

Enter the Full Title of the study.

1.3 **Principal Investigator:** Vidya Krishnan

HSR Certification Status: Certified **HSR Certification Expiration Date:** 12/7/2022 ;

COI Expire Date: 2/5/2022 ; **COI Yes or No:** No ; **COI Management Plan:** ; **PI Non-Compliance:** Yes

The PI must be a MetroHealth Staff person or have privileges to practice at MHS. The PI must assume full responsibility for the conduct of the study.

1.4 **Key Personnel:**

	Name	CREC Status	CREC Expiration	COI	COI Expire	Management Plan?	Study Roles	Employer Name	Non-Compliance
View	Faiza Khalid	Certified	6/1/2023	no	1/21/2022		Interviewer (Survey, Focus Group) eIRB Notification Recipient Obtaining Informed Consent	The MetroHealth System	

Add additional Staff as needed.

Update to add Study Roles

If using Epic, add role of DRA to one person

	Name	CREC Status	CREC Expiration	COI	COI Expire	Management Plan?	Study Roles	Employer Name	Non-Compliance
View	Charles Ebersbacher	N/A	1/18/2023	no	4/14/2022		Co-investigator DRA (only one) Obtaining Informed Consent Co-investigator	The MetroHealth System	

1.5 Type of Research:
Survey Study

1.6 If "Other" Type of Research Please Explain:

View: 01-01 Study Information

1.1 Study Information:

1.7 * Department-What Department approvals are required?
Name
Medicine

1.9 Definitions to keep in mind when selecting the degree of risk:

Minimal Risk is defined in 45CFR46 and in FDA regulations 21CFR50.3 as:
Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

*** Degree of Risk: (This is the investigator's assessment of the risks involved in the research which will informed the IRB Decision but which will not automatically**

Select most appropriate one.

be accepted. The Board is the final arbiter of risk. The risk level will be set by the IRB staff at the time of approval.)

Name

○ Risk

◉ Not Greater Than Minimal Risk

1.10 * Type of IRB Review Requested:
Expedited

Select one. If you select Exempt or Expedited you will be taken to that section when you hit continue.

View: 01-02 Study Information

1.2 Study Information:

1.11 Will you require access to Epic to conduct this study? ◉ **Yes** ○ No

*****The DRA's employee number must be listed on their registration form.*****

If you answer this question yes you will need to identify a Designated Records Administrator one person only.

Please add the role of "DRA" to one study staff member on page 1 of the application.

1.12 Is the Principal Investigator a resident or trainee?

○ Yes ◉ **No**

Please check yes or no.

NOTE: Residents, Fellows, and non-MHS Personnel cannot be listed as the Principal Investigator

View: 01-03 Study Information

1.3 Study Information:

1.13 * **Will CRU Be Used:**
No *If you answer yes to this question this application will be sent to the CRU for review after departmental review and before it is submitted to the IRB.*

Will the CRU be used?

1.14 * **Has this research protocol ever been submitted to another CASE affiliated IRB (i.e. UH, CCF, VA or CASE)?**
No

If this study has been reviewed at another CASE affiliated IRB you should answer yes.

1.15 If yes, was it:

Select one from drop down menu.

1.16 Please supply the following information: At which institution was it approved? If it was disapproved, why was it disapproved?

Please attach the Approval letter/letters from other IRBs (i.e. UH, CCF, VA or CASE):

Name	Description
There are no items to display	

What institutions have approved this study. If it has been disapproved, please give a brief explanation of why study was disapproved.

1.17

Please attach approval letter/letters.

View: 01-04 Study Information

1.4 Study Information

These Questions are specifically about the adequacy of resources, are there the necessary resources to complete this study? There are two questions which focus on nursing resources. If this research will require the use of nursing resources then the Nursing Resources Form found on the IRB Home Page under forms and templates will need to be completed and attached to this research application.

1.18 **Can you assure the IRB that there are adequate numbers of qualified staff to conduct this research?**

(●) **Yes** ( ) No

Please answer yes or no. This is an assurance to the IRB.

1.19 **How will the investigator ensure that persons assisting with the research were adequately informed about the protocol and their research-related duties and functions and requirements for maintaining the confidentiality of all data?**

The investigators have met and discussed the study, and plan on weekly research meetings. We discussed the project with the pulmonary rehab coordinator, who agrees to the research, but will not need to use any more time/effort towards the project. The pulmonary rehabilitation staff and coordinators are not directly involved in data collection, analysis or obtaining informed consents.

i.e. investigator meeting, formal protocol review with PI, monitor, sponsor.

1.20 **Will the PI and study staff have sufficient time to conduct and complete the research?**

(●) **Yes** ( ) No

Please answer yes or no. This is an assurance to the IRB.

1.21 **What facilities are available to conduct the research? Are they adequate? Please describe.**

Pulmonary rehabilitation cohort will be used. The rehab is located on the 3rd floor, within the pulmonary/heart and vascular clinic. Desk/offices are available with work computers in BG-3.

Please describe the facilities, i.e. lab, procedure room, chemo treatment room.

Nursing Resources:

1.22 **Is this study using MetroHealth staff nurse time or labor ? (i.e. giving medcations, teaching, or additional documentation)**

( ) Yes (●) **No**

This is in addition to the time of the study/research nurse.

1.23 **Attach Nursing Resources Form here:**

Click here for Nursing Resources form

Open the form, Complete the form and save it to your files then attach it to the study by hitting the browse file and selecting the file and hitting OK.

Click here for the MHS Policy

View: 05-00 Funding Information I

5.0 Funding Information I:

All Research Projects must have an identified funding source!

5.1 Is this research externally funded? No — *Check one*

Research can be both externally and internally funded so you can answer yes to both 5.1 and 5.6.

5.2 Types Of External Funding: — Check all that apply.

Name

There are no items to display

5.3 If other, external funding please explain: — If other please describe.

5.4 Sponsor Information: — Please supply this information as your application can not be processed without it.

Name Sponsor/Agency | Address | Telephone | FAX | Contact Person

There are no items to display

5.5 Have you received and/or submitted a Notice of Award or Contract? — *Select one from drop down menu.*

No

Attach notice of award.

If yes, attach your Notice of Award letter here (not your grant):

Name | Version

There are no items to display

View: 05-01 Funding Information II

5.1 Funding Information II

5.6 ***Is Research Internally Funded (internal funding is any MetroHealth System or MetroHealth Foundation funds):*** — *Check one, research can be both externally and internally funded so you can answer yes to both 5.1 and 5.6.*

◉ ***Yes*** ○ *No*

5.7 **Internal Funding Sources List:**
Internal Funding Source
Department Operating Budget

Check all the apply.

5.8 **If a MetroHealth Foundation funds or any MetroHealth System funds are being used, has department approval been received?**
◉ **Yes** ○ No

Check yes or no.

5.9 **If a MetroHealth Foundation funds or any MetroHealth System funds are being used indicate the Account Number:**
Pulmonary Education Fund #21401004

Please enter the account number if this applies.

5.10 *** Are there current Conflict of Interest Forms for all Key Personnel? [It is the responsibility of the Principal Investigator to ascertain this information and check this box.]**
◉ **Yes** ○ No

This question is not asking if there are COI forms for all Key Personnel it is asking if all Key Personnel have current COI forms so that any SFI is reported and can be dealt with if a management plan is need or reporting to NIH is required.

In order to submit a new protocol all COI Forms for key personnel and investigators must be current = provide up to date information.

5.11 **Please check below any Conflicts of Interest (Financial) you as Principal Investigator or your study staff [Co-Investigator, Coordinators, Other Study Staff] may have on this Study:**
Potential Conflict of Interest
None of the above options apply and there are no other financial conflicts of interest in the conduct of this research.

This question pertains to this study and is not a general question. Check all that apply.

You and/or your study staff will need to file a Conflict of Interest Disclosure Form annually.

If anyone working on this study has a Conflict of Interest or a perceived conflict. This information will need to be included in the consent form i.e. company is paying MHS to do this study.

5.12 **Please attach a copy of your grant application here:**
Name Description
There are no items to display

You must attach a copy of your grant application here (i.e. NIH Grant Application).

You have the option to attach a copy of the budget, clinical trial account authorization form, contract and Approval letter(s) now or you can email them to your grants management specialist in the RABO office.

Copies of all RABO forms are available at:

http://www.metrohealthresearch.org/raboforms.html

View: 06-00 Performance Site Information

6.0 Performance Site Information:

6.1 At what sites will the study team be performing this research, (please enter information about all non-MHS sites in 5.2):

Select all that apply. If you select other please enter information about that site in question 6.2.

Name

The MetroHealth System

If this study is being done at MetroHealth where is it being done give the physical location (i.e. 8B, ED, Broadway, Old Brooklyn, PICU, Cath Lab):

Surveys will be sent electronically to patients via MyChart, or through regular US mail. The patients who may be included in the study will be the cohort of patients undergoing Pulmonary Rehab (Hamann 3rd floor).

Where is the research going to be done? What physical location on the Main campus or the community health centers?

6.2 Please provide information about other external sites here:

Please enter contact information. Please include name of facility, address and department.

Name of Site | Address | Telephone Number

There are no items to display

6.3 If you are doing this research at an external site does this site have an IRB?

Select yes or no.

○ Yes ○ No

6.4 If the External Site has an IRB will that IRB defer review to the MHS IRB?

This only applies if there is no IRB or if there is a legal agreement between

○ Yes ○ No

institutions permitting a reciprocal review, i.e. CASE.

6.5 Attach letter from external site agreeing to permit the MHS to review this protocol:

Attach letter.

Name | Description

There are no items to display

6.6 Has the external site granted permission for the research to be conducted?

○ Yes ○ No

This applies to sites where there is no IRB and the investigator must get a letter from the site that gives permission to conduct the research at the site.

6.7 Attach letter from external site granting permission for the research to be conducted:

Attach letter of support.

Name | Description

There are no items to display

View: 06-01 Performance Site Information

6.1 Performance Site Information

6.8 Is MHS the lead institution of a multi-site study? ○ Yes ◉ **No**

Please answer yes or no.

6.9 If yes, is there a plan to communicate information obtained through research that might be relevant to the protection of human subjects, including a plan to provide the IRB with information on unanticipated events, interim results, and protocol modifications.

Please answer yes or no.

○ **Yes** ○ **No**

6.10 Please give a detailed explanation of the above plan:

This plan must give the IRB enough information to decide if

the plan is appropriate and adequate.

6.11 Will the Principal Investigator conduct this study at any location outside the United States of America?

○ Yes ◉ **No**

Answer these questions only if there are research sites outside the USA.

6.12 Country, City, and address:

Country Address of Research Facility

There are no items to display

Give country and location.

View: 07-00 Research Objectives and Background

7.0 Research Objectives and Background:

7.1 * ABSTRACT: Please give the IRB a 500 word Abstract that contains the specific objectives of the study.

This is your abstract also known as a synopsis from an industry sponsored study. Please limit to 500 words.

Background:

Sleep disorders including poor quality of sleep are common in patients with heart disease, chronic obstructive pulmonary disease (COPD) and, possibly, other chronic lung disorders. These patients complain of difficulty sleeping; sleep fragmentation, often related to symptoms such as cough, sputum production or shortness of breath. Patients with COPD and heart failure commonly have other abnormalities such as nocturnal oxygen desaturation that may further worsen sleep disturbances. Moreover, sleep disordered breathing (SDB), like obstructive sleep apnea syndrome (OSA), has been linked to higher morbidity and mortality if COPD is present (Overlap syndrome). In patients with COPD and heart failure, cardiac-pulmonary rehabilitation (CP-R) has important health benefits such as improvement in symptoms, exercise tolerance, and quality of life. However, the effect of CP-R on sleep quality is controversial. Disturbed sleep is associated with frequent exacerbations, increase in the severity of disease and increased mortality in COPD and heart failure patients. Sleep quality is a good predictor of quality of life in patients with stable COPD.

We hypothesize that CP-R results in improved sleep quality in patients with chronic lung and heart disease which may be an important contributor to improved health outcomes after CP-R

Goals and objectives:

The purposes of this study are to:
1) Evaluate the effect of CP-R on sleep quality in patients with chronic lung and heart diseases.
2) Determine the longevity of sleep quality improvement by conducting a follow-up survey
3) Determine if sleep quality impairment correlates with positive screen for sleep apnea.

7.2 *** What are the specific aims of this study i.e. what are the question(s) this research intends to answer? Provide at a maximum 3 primary and 3 secondary aims.**

This is your Hypothesis also know as your aims (NIH) or safety and efficacy aims (industry). Please list no more than 3 primary and 3 secondary clearly label these aims primary and secondary.

Primary aims:
1. Does cardiac-pulmonary rehabilitation (CP-R) lead to improved sleep quality?
2. Does the improvement in sleep quality persist after 3 months?
3. Is sleep impairment associated with positive screen for sleep apnea?

Secondary aims:
1. Does the improvement in sleep quality correlates with improvement in excessive daytime sleepiness, health related quality of life as determined by COPD assessment test score for COPD patients, and short form health survey-36 for cardiac patients
2. Does the improvement in health related quality of life persist after 3 month post pulmonary rehabilitation.

7.3 **Please provide a summary of the present knowledge relevant to the research and make citation to any applicable scientific literature:**

This is your literature search and bibliography. Also known as Background and significance (NIH) or Introductory Section from industry sponsored trial.

In patients with chronic lung and heart diseases, CP-R has important health benefits such as improvement in symptoms, exercise tolerance, and quality of life.(1) However, the effect of CP-R on sleep quality is controversial. Disturbed sleep is associated with, frequent exacerbations, increase in the severity of disease and increased mortality in COPD.(2) Sleep quality is a good predictor of quality of life in patients with stable COPD.(3)Increase in physical activity improves sleep in healthy individuals.(4) However, there has been little investigation into non-pharmacological methods to improve sleep quality in patients with COPD. It is also uncertain, how long the beneficial effects of pulmonary rehabilitation on sleep quality, if any, usually last. In an observational study, CP-R was associated with a statistically significant improvement in sleep quality.(1) Other researchers did not find any significant benefit of CP-R on quality of sleep.(5, 6) Due to lack of robust data, we sought to find the effect of CP-R on sleep quality.

1. Soler X, Diaz-Piedra C, Ries AL. Pulmonary rehabilitation improves sleep quality in chronic lung disease. COPD. 2013;10(2):156-63.
2. Omachi TA, Blanc PD, Claman DM, Chen H, Yelin EH, Julian L, et al. Disturbed sleep among COPD patients is longitudinally associated with mortality and adverse COPD outcomes. Sleep Med. 2012;13(5):476-83.
3. Scharf SM, Maimon N, Simon-Tuval T, Bernhard-Scharf BJ, Reuveni H, Tarasiuk A. Sleep quality predicts quality of life in chronic obstructive pulmonary disease. Int J Chron Obstruct Pulmon Dis. 2010;6:1-12.
4. Youngstedt SD, O'Connor PJ, Dishman RK. The effects of acute exercise on sleep: a quantitative synthesis. Sleep. 1997;20(3):203-14.
5. McDonnell LM, Hogg L, McDonnell L, White P. Pulmonary rehabilitation and sleep quality: a before and after controlled study of patients with chronic obstructive pulmonary disease. NPJ Prim Care Respir Med. 2014;24:14028.
6. Cox N, Pepin V, Burge A, Mahal A, Hill C, Lee A, et al. Pulmonary Rehabilitation Does Not Improve Objective Measures of Sleep Quality in People with Chronic Obstructive Pulmonary Disease. A66 PULMONARY REHABILITATION: CLINICAL STUDIES IN COPD: American Thoracic Society; 2018. p. A2157-A.

7.4 Option to Upload Documents related to question 7.3:

If it is easier to attach your response to question 7.3 please do so here. *Please limit to three pages.*

Name	Description
There are no items to display	

View: 08-00 Methods and Procedures I

8.0 Methods and Procedures I:

8.1 Will this research involve the following Social-Behavioral Procedures:

Check all that apply.

Name
Surveys/Questionnaires

8.2 Will this research involved any of the following Medical Procedures/Considerations:

Check all that apply.

Name
None of the above Medical Procedures/Considerations Apply to this Study

8.3 Identify Data Collection types for this study:

Check all that apply.

Name
Interviews, questionnaires or psychological tests

Note if you are doing, recordings, Video-Recording/Photographs then

subjects will need to sign the MetroHealth Audio-Video Consent form. See the IRB Forms and Templates.

View: 08-01 Methods and Procedures II

8.1 Methods and Procedures II:

8.4 * **Please specify in detail the methods and procedures that are involved in this research:**

If this field is not completed your protocol will not be reviewed. Do not enter N/A. Please describe what methods and procedures will be involved in this research.

Methodology:

Study Population:
This study will collect prospective data from patients being referred to Metrohealth's Pulmonary rehabilitation center.

Data collection plan:
The study will use data from questionnaires filled by patients before and after completion of pulmonary rehabilitation. A 3-month follow up survey using the same questionnaires will be conducted. The questionnaires that will be used include Pittsburgh sleep quality index (PSQI), Epworth sleepiness scale (ESS), Berlin questionnaire, COPD assessment test, Short form health survey-36 (SF-36), hospital induced anxiety and depression scale (HADS) and insomnia severity index (ISI). The questionnaires will be sent to the patients either through MyChart messaging or direct mail with a memo cover-sheet explaining the research study and voluntary participation. The surveys will be available to the participants through MyChart for four weeks after being sent out to give them ample opportunity to participate. The survey will not pop up each time with MyChart login but patients who have not filled the questionnaires will get a weekly reminder to complete the questionnaires when they login to MyChart. However, if the patient declines to participate in the study, the survey will not pop up again and no reminder will be sent. Since the questionnaires are being used to track changes before and after pulmonary rehabilitation, the participants will not be able to take the survey more than once at each point (beginning, end and 3-months post completion of pulmonary rehabilitation). All patients regardless of contact method (via mail or MyChart) will be able to bring printed and filled questionnaires on Day 1 of pulmonary rehabilitation. However, if a MyChart user prefers to fill the questionnaires online through MyChart, s/he will be able to do so. Follow up surveys at the end of pulmonary rehabilitation and 3-months post-completion will be returned via mail or MyChart depending on whether patients have signed up for MyChart or not. For MyChart users, the questionnaires will remain

available for four weeks at each point, as stated earlier. A copy of all the questionnaires being used in the study and the memo cover-sheet will be uploaded with IRB application. We will collect existing data for patients who consent to participate in the study including type and severity of disease. If the patient does not consent to the study, no data will be collected.
The de-identified data will be stored in a secure Health Insurance Portability and Accountability Act (HIPAA) complaint database.

8.5 Does this study only involve the use of existing/retrospective data/specimens?
No

Check yes or no.

8.6 Describe in <u>detail</u> the study design also known as the experimental flow. Include all study procedures a subject will go through, in order of sequence and timing, including frequency of visits, duration of visits, length of subject participation etc. *Please Note this needs to be written for an educated person who is not an expert in the field, do not exceed 300 words*:

This is also known as NIH Experimental Procedure section or Clinical Trial Procedure/Experimental Flow section. Do not just attach documents in response to this question you must do a study design summary for IRB Review.

For the patient who have signed up for MyChart and are scheduled to start pulmonary rehabilitation, questionnaires including Pittsburgh sleep quality Index (PSQI), Epworth sleepiness scale (ESS), COPD assessment test (CAT), Short form health survey-36 (SF-36), Hospital anxiety and depression scale (HADS), insomnia severity index (ISI) and Berlin Questionnaire will be sent using MyChart. A recruitment letter will also accompany the questionnaires. For the rest of the patients, the questionnaires will be mailed. Questionnaires will be accompanied by a non-return cover memo. The packet will have the subject's unique patient identifier code on it only (no PHI). Patient will then return the filled questionnaires on Day 1 of cardiac and pulmonary rehabilitation. However, MyChart users will have the option to return the surveys online through MyChart prior to starting pulmonary rehabilitation if they wish to do so. The rest of the patients will need to print out the questionnaires. Another patient packet including the same unfilled questionnaires with a stamped return envelope will be sent to MyChart non-users at the end of pulmonary rehabilitation and then after 3 months.
For MyChart users, MyChart will be used to send the unfilled surveys at the end of pulmonary rehab and after 3 months of completion.

It will take 40-45 minutes to complete all the questionnaires each time. The completed questionnaires will be stored in the PI's office (lock protected). Questionnaire results will be used in research database. Initial consent to participate is for the entire study. We will collect existing data for patients who consent to participate in the study including type and severity of disease as stated in non-return cover memo. For non-consenting patients, no data will be collected.

8.7 Please attach study design/subject visit schedule here:

Name	Description
Study Design | History	

If you have an electronic schedule of study visits and/or procedures please attach here.

View: 09-00 Inclusion/Exclusion Criteria

9.0 Inclusion/Exclusion Criteria:

9.1 What are the inclusion criteria? Put this information in bullet form:

Please list inclusion criteria.

Inclusion criteria:
- Age > 18 years
- Patient who are willing to participate in follow-up survey 3 months after completion of PR.
- Patients who complete rehabilitation for at least 8 weeks.

9.2 What are exclusion criteria? Put this information in bullet form:

Please list exclusion criteria.

Exclusion criteria:
- **Not meeting inclusion criteria**

9.3 How will subject eligibility be determined and by whom?

Please describe in detail.

Patients meeting inclusion criteria and willing to participate in the study will be eligible for the study.
Co-investigator and the PI will determine the eligibility to participate in the study.

9.4 Will you exclude women and minorities, or persons under 21 from enrollment?

Check yes or no.

No

9.5 If yes, which groups are you excluding? Provide justification for your decision.

List groups to be excluded then provide justification.

9.6 Attach Documents:

Name	Description
There are no items to display	

If you are unable to fit your answers in the text boxes provided please attach as a word document.

View: 10-00 Risk/Benefits

10.0 Assessment of Risk I:

10.1 Identify and distinguish between those procedures that are standard versus those that are experimental. Include the frequency and duration of each activity and the total length of subject participation:

Please distinguish between those procedures that are standard versus those that are experimental. Describe in detail all experimental procedures.

The questionnaires including Pittsburgh sleep quality index, Epworth sleepiness scale, Berlin questionnaire, Health related quality of life questionnaires (Short form health survey-36 (SF-36) for cardiac patients and COPD assessment test for COPD patients), and hospital anxiety and depression scale and insomnia severity index (ISI) will be used for research purpose.
Patient will be asked to fill the questionnaires at baseline (start of pulmonary rehab), at completion of pulmonary rehabilitation and 3 months after completion of pulmonary rehabilitation. It will take 40-45 minutes to complete the questionnaires/ surveys each time.

All the patients will complete standard pulmonary rehabilitation as prescribed by the physician.

10.2 Describe any therapeutic alternatives to the research that may exist. How are they different from those procedures that subjects would normally undergo? Patients may elect not to participate in the survey study.

Describe any therapeutic alternatives. Can subjects receive this drug or device outside of a research study?

10.3 What are the outcome variables and how will they be analyzed? What are the statistical and analytical methods that will be used? *Note this section can be copied from the NIH Grant Application or from the Statistical and Analytical Methods section of the industry trial protocol.*

Define outcomes and describe data analysis, please include a power calculation.

We will analyze the data using SPSS and STATA. The primary outcome measure will be the change in individual Pittsburgh sleep quality index scores at the beginning, end and after 3-months of cardiac and pulmonary rehabilitation. We will also screen patients for sleep apnea prior to starting rehabilitation using Berlin questionnaire. Secondary outcome measures will include changes in the hospital anxiety and depression scale, insomnia severity index, COPD assessment test, Epworth sleepiness scale, short form survery-36, insomnia severity index at the beginning, end and after 3-months of cardiac and pulmonary rehabilitation. A paired-sample Student t-test will be used to compare means before and after the CP-R. Pearson's product co-efficient (r) will be used to analyze association between changes in Pittsburgh sleep quality index, hospital anxiety and depression scale, COPD assessment test, Epworth sleepiness scale, Short form health survey-36 at the beginning, in the CP-R cohort.

We are planning a study of a continuous response variable from matched pairs of study subjects. Prior data indicate that the difference in the response of matched pairs is normally distributed with standard deviation 4.6. If the true difference in the mean

response of matched pairs is 3, we will need to study 27 pairs of subjects to be able to reject the null hypothesis that this response difference is zero with probability (power) 0.9 (90%). The Type I error probability associated with this test of this null hypothesis is 0.05.

10.4 If the above requested information does not fit in the text box please attach a word document here:

If the requested information does not fit in the text box please attach a word document.

Name Description

There are no items to display

View: 10-01 Risk/Benefits

10.1 Assessment of Risk II:

10.5 List and quantitate the risks involved for each experimental procedure in bullet form. Identify risks as common (greater than 10%) uncommon (greater than 1% up to and including 10 %) rare (1% or less). This must match the risks listed in the Consent Form:
Minimal risk of patient data being compromised. Emotional and psychological risks are rare. Participation is completely voluntary and patients can skip the questions they do not wish to answer.

Select all that apply.

10.6 Are there defined stopping rules? ○ Yes ◉ **No**

Describe in enough detail for the IRB to assess safety.

What are the stopping rules for the study? What are the conditions under which a subject will be withdrawn from the study for safety reasons, i.e. disease progression?
Not applicable

What findings, events, or conditions would require a research subject to be removed from the study? (i.e. disease progression)
Not applicable

10.7 What Category of risk will study participants be exposed too?

Should be consistent with risks listed in the Consent Form.

Name
Psychological
Privacy

10.8 **If Other listed above please specify:**
Minimal risk of patient data being compromised. Emotional and psychological risks are rare. Participation is completely voluntary and patients can skip the questions they do not wish to answer.

A text box is provided for further explanation.

10.9 **Describe the availability of medical or psychological services that participants might require as a consequence of participation in this the research:**
Medical care (including hospitalization) is available if the patient is injured or becomes ill because of the research procedures. This medical care is not free. The patient will be responsible for the costs. The patient may call the Manager of Contracts and Budgets at (216) 778-5219 with any questions about the cost of treatment.

A text box is provided for further explanation.

10.10 **Describe in detail any measures in place to minimize or protect against the exposure of study subjects to these risks:**
Paper data will be securely stored in locked cabinets in PI's office, which is a locked office when not occupied, and electronic data will be stored in RedCap and a MHS secure, network drive on the G: drive (Krishnan Research in the pulmonary folder). In order to minimize psychological risks, participation is completely voluntary and patients can skip the questions they do not wish to answer.

Discuss any provisions for intervention in the event of an Adverse Event i.e. stopping rules.

10.11 **Please add any documents related to the above questions:**

Name	Description
There are no items to display	

If your answers to the above questions are too long for the space provided please attach them here.

View: 10-02 Risk/Benefits

10.2 Benefits:

10.12 **Describe the potential benefits to the subject as a result of participating in this research. If there is no direct benefit to subjects please state that as well:** ***Note: payment or compensation to subjects for participation is not to be considered a potential benefit.***
If subject is found to be at high risk for obstructive sleep apnea or other sleep disorders, then the subject will be notified so they can contact their primary care provider and undergo testing and treatment for sleep disorders. Patients will be able to assess themselves if there is any improvement in sleep quality after completing pulmonary rehabilitation and whether the beneficial effects of pulmonary rehab last 3-months post completion.

Describe potential benefits to the study subjects.

10.13 **Describe the potential benefits to society as result of this research:**
If pulmonary rehabilitation does improve sleep quality, that can be added as

Describe potential benefits to society.

another benefit of completing the rehabilitation program. Patient who complete the rehabilitation program, report improvement in health related quality of life, anxiety and depression scores. However, it is not known how long do these beneficial effects last. Therefore, completing a 3 month follow up might help in understanding the long-term benefits of pulmonary rehabilitation. Prevalence of sleep apnea is not known in pulmonary rehabilitation cohort. Screening this cohort for sleep apnea would be an added benefit as it would provide an opportunity to identify patients with increase risk of sleep apnea.

10.14 What is the risk/benefit ratio of the research?

Discuss why the risks are reasonable in relation to the anticipated benefits.

The benefits of pulmonary rehabilitation are well documented that there is short-term improvement in respiratory symptoms and quality of life. This research study would help in understanding the impact of pulmonary rehabilitation on sleep quality as well as long-term benefits of pulmonary rehabilitation. The research study will not impact the pulmonary rehabilitation protocol itself nor will it take away time from the rehabilitation program. This study will also screen patients for sleep apnea. There is minimal risk of compromise of patient data which would be expected with any research study with similar design. However, the benefits outweigh the risks associated with the study.

10.15 Attach Documents:

Attach documents here.

Name	Description
There are no items to display	

View: 11-00 Study Participant Information I

11.0 Study Participant Information I:

11.1 How will the Principal Investigator assure he/she has access to a population that would allow recruitment of the required number of study participants (i.e. prep for research):

How does the PI know he/she has the required number of subjects?

Pulmonary rehabilitation patients are within the scope of the PI's practice. Each pulmonary rehabilitation group has 5-10 participants. The program is usually 8 weeks long. 2 new groups start each week. Approximately 50% of the participants complete the rehabilitation program.

For our study to have sufficient power, we need 27 patients.

11.2

Please give the total #of subjects to be enrolled at all sites and anticipated subjects to be enrolled at MHS.

Anticipated number of subjects (all sites): [enter a number]

80

Anticipated number of subjects to be enrolled at MHS: [enter a number]
80

Anticipated number of potential subjects to be approached: [enter a number]
80

11.3 If this is a multi-site study, how many sites will there be? [enter a number] How many total sites?

11.4 Subject Characteristics: Check all that apply
Subject Population Categories
Outpatients

11.5 Subject Source: Check all that apply
Subject Source Characteristics
Subjects from the Practice of the Principal Investigator

11.6 If "other" list above in either 11.4 or 11.5 please describe: *If applicable please describe.*

View: 12-00 Study Participant Information II

12.0 Study Participant Information II:

12.1 Select age range of study participants: Check all that apply.
Subject Age Range
18 - 64
65 - 89
90+

12.2 *** Will the study enroll vulnerable subject groups?** Check yes or no.
Yes

*** Will you be enrolling Children?**
○ **Yes** ◉ **No**

*** Will you be enrolling Pregnant Women and/or Fetuses?**
○ **Yes** ◉ **No**

*** Will you be enrolling decisionally impaired subjects?**
○ **Yes** ◉ **No**

*** Will you be enrolling Prisoners?** ○ **Yes** ◉ **No**

12.3 **Please identify any vulnerable populations participating in the study:** Check all that apply.
Vulnerable Populations
Poor / Uninsured
Elderly
Employees
Students
Minorities

12.4 **If you selected "other" above please describe:** *Please describe other.*

If you are going to enroll <u>any</u> vulnerable populations please describe the safeguards you will put in place to protect these vulnerable Populations. *Please enter a detailed plan.*
12.5 All subjects will be treated equally. The participants will consent to study by bringing questionnaire forms on the first day of their cardiac-pulmonary rehabilitation visit. All subjects will be aware that participation is completely voluntary.

View: 13-00 Recruitment I

13.0 Recruitment I:

All external advertisements (for radio, print media or TV) must be approved by MHS Communications Department prior to submission to the IRB so the IRB can see the final advertisement or script. All Advertisements on the MIV or On Hold messaging must be approved by the IRB before they are placed. You may not advertise a study which is not approved by the IRB. Please note that all studies which have a contract which an external sponsor must have that contract signed before any advertising can be done.

13.1 Recruitment Methods/Sources:

Check all that apply.

Name
Research Match
Other

13.2 If "Other" checked in 13.1 please explain:

Please explain what other means.

Patients who are anticipated to begin pulmonary rehabilitation will be approached via MyChart or regular mail to voluntarily participate in the study.

13.3 Describe in detail all recruitment strategies for each subject group (as listed in Section 11.0) selected for this research:

Please describe recruitment strategies in detail.

Patients who are anticipated to begin pulmonary rehabilitation will be approached either via mail or MyChart or on the first day of cardiac and pulmonary rehabilitation orientation with a patient packet containing non-return cover memo sheet, recruitment letter and questionnaires. For our research study to have sufficient power we need at least 27 subjects. However, the completing rate of pulmonary rehabilitation is 50%. Additionally some of the participants who initially agreed to participate in the study may fail to return the follow up questionnaires at the end and after 3-months of pulmonary rehabilitation. For these reasons, we plan on approaching 80 pulmonary rehabilitation participants.

As we are also planning to use Research match, an amendment will be filed at a later date to add Research Match.

13.4 What measures will be taken during the recruitment process to safeguard against the potential coercion or appearance of coercion of human subjects, particularly vulnerable subject groups?

Please give an explanation of safeguards to be used.

Patients will get a non-return cover memo and a recruitment letter that explains that participation is voluntary and will not affect their therapy. All patients will be treated equally. MyChart messages will clearly be marked as "RESEARCH STUDY - OPTIONAL" in subject line and in the memo.

13.5 Incentives to Subjects: Will subjects receive any incentives (payments, free service, gifts, etc.) for participation in the research?

This information must mirror the consent form language.

Yes

13.6 If yes, please describe these incentives and how they will be disbursed: *Note: payment or compensation to subjects for participation is not to be considered a potential benefit.*

Describe incentives, if they are to be pro-rated based on visits completed please give that information. This information must mirror consent form language.

Participants will be eligible to receive $20 total in the form of MetroHealth dining gift card, to be given at the end of the C-PR and 3-months post C-PR.

•$10 for completion of questionnaires/surveys at baseline after completion of C-PR
•$10 for completion of questionnaires/surveys at baseline 3 months after completion of C-PR

$10 gift cards will be given to the participants at the end of their exit session after the return the completed questionnaires. Participants will be mailed $10 gift card after they return the completed questionnaires, 3-months post rehabilitation.

For the participants who have completed and returned the exit C-PR questionnaires but either have not returned 3-month post C-PR questionnaires or not at the 3-month post C-PR mark will be mailed $10 metrohealth dining gift card.

13.7 Please attach copies of all recruitment/advertising materials and verbal scripts:

Name	Version
Recruitment letter sent before calling (1).docx | History	0.02

Attach copies of all recruitment and advertising materials.

View: 13-01 Recruitment II

13.1 Recruitment II:

13.8 Expense to Subjects: Will subjects incur any expenses as a result of participation in the study or will they be billed for any study-related procedures?
No

Check yes or no, make sure this information is in the consent.

13.9 If yes, please describe the expenses or charges that subjects will be assessed:

Please provide information regarding expenses to subjects and add information to consent.

13.10 Compensation For Injury: If applicable, will funding be available to compensate subjects for injuries sustained as a result of participation in this research?
No

Check yes or no, make sure this information is in the consent.

13.11 Who will cover the costs related to any injuries sustained due to participation in the study?
No injuries are expected or anticipated specifically due to the research study. The risks of injury while going through pulmonary rehab, although minimal, are present. These risks are independent of the research study. However, in case of any injury subjects and their insurance would be responsible for any costs.

Please describe in detail. Examples subjects or their insurance company, study sponsor.

View: 14-00 Data Collection

14.0 Data Collection:

14.1 A. What type of data will you be collecting as part of this research?

Existing data must be in place or on the shelf prior to the submission of the research protocol to the IRB.

Prospective data is collected in real time.

Will you collect existing data?

or

Will you collect prospective data?
○ Yes ○ No

or

Will you collect both existing and prospective data? ◉ **Yes** ○ No

***Definitions:* Data are considered to be existing data only if they were in place or "on the shelf" prior to the submission of the research protocol to the IRB. Data are considered prospective if they are created and collected as part of the research i.e. from surveys, questionnaires.**

Tell the IRB why you are collecting this data i.e. to verify inclusion criteria.

B. Why are you collecting this data?

What will be the purpose of collecting and/or reviewing the data (new data or existing data).
To gather information about effects of pulmonary rehabilitation on sleep quality and if the benefits of pulmonary rehabilitation last after 3 months of completing pulmonary rehabilitation.

14.2 If you are collecting existing data:

Specify the types of existing data you will use in this study.

Specify the type(s) of existing data sources you will use (medical records, school records, publicly available records, existing database). If you are collecting data from an exisitng database and that database contains PHI, you must provide the IRB Approval letter (attach to Section 27.00 Additional Documents).
EPIC

Time frame i.e. last 10 years or from 1990-2000.

What is the timeframe of the existing data you wish to review? (i.e. 2000-2006)
Entire available medical chart for patient (past medical history may extend to patient's birth).

14.3 If you are collecting prospective data:

Where or how will the data be obtained? (i.e. surveys, questionnaires, psychological tests)
Surveys - sent through MyChart or regular mail.

Where will data be obtained? i.e. survey.

14.4 How will the data you collect be identified?

Types of Data Identification:
Name
Deidentified/Confidential- Data will be linked to subject(s) via a code or indirect identifier (i.e. study IDs or numbers)

Please select how your subject data will be identified.

14.5 Will the information collected from these records be linked to any research subjects by identifiers? (i.e. name, MRN#, DOB)
(●) **Yes** ( ) No

Will your data be linked to subjects?

Please answer questions about the security of the data in section 15.00

14.6 If subject data will be deindentified using a code will there be a link or a key? Please describe. Who will have the key and where will the key be kept?
Electronic data containing PHI will be stored in RedCap. The de-identified data sheet will list the unique study ID number (key) in order to match the data to its subject listed in RedCap. The key will be stored in G drive in a password protected file. Study staff will have access to the study key file.

Under the HIPAA Regulations, deidentified key codes must be stores separately from data & must not be kept on paper, but electronically. The MetroHealth Research Informatics Support should be contacted at REDcap@metrohealth.org for assistance. They will assist personnel in developing a key in MetroHealth REDcap database. They can also assist with training & development for your study. REDcap is a free database provided in part by the Case CTSA.

Explain how Data will be linked.

14.7 Data Collection Form(s):

Name	Version
PR project excel sheet.xlsx | History	0.02

Add data collection forms and CRFs.

View: 15-00 Data Security I

15.0 Data Security I:

It is imperative that the IRB is proactive and consistent in protecting all research data containing Protected Health Information(PHI).

15.1 * Are the records for this study (some or all) electronic? ◉ **Yes** ○ **No**

What is Protected Health Information? The Privacy Rule protects certain information that covered entities use and disclose. This information is called protected health information (PHI), which is generally individually identifiable health information that is transmitted by, or maintained in, electronic media or any other form or medium. This information must relate to 1) the past, present, or future physical or mental health, or condition of an individual; 2) provision of health care to an individual; or 3) payment for the provision of health care to an individual. If the information identifies or provides a reasonable basis to believe it can be used to identify an individual, it is considered individually identifiable health information.

The following questions must be answered when submitting a new protocol.

15.2 * Are you collecting PHI? ◉ **Yes** ○ No

15.3 Is any PHI going to be stored as paper files? ◉ **Yes** ○ No

15.4 Is any PHI going to be stored in an electronic file format? (i.e. access, excel) ◉ **Yes** ○ **No**

15.5 Is your data being stored on a laptop computer? ○ Yes ◉ **No**

15.6 Will you be using RedCap to store your data? ◉ **Yes** ○ **No**

Which RedCap Database will you be using?

Name

MetroHealth

15.7 Are you planning to store your data using a portable storage device?(i.e. jump drive, external hard drive, cd) ○ Yes ◉ **No**

Per current MetroHealth Policy PHI may not be stored on portable electronic devices.

15.8 Are there any circumstances under which you would want to remove data from MHS? (i.e. take data home to work on it) Give details below. Please note identified data can't be removed from MHS unless there is permission granted in the HIPAA Authorization. If you are unsure about what is identified data please consult the IRB staff. If you feel you will need access to your data when you are off campus you should ask the MHS IT Department located in Rammelkamp

room R 134 about VPN access.

○ Yes ◉ **No**

If you answered yes to question 15.8, please explain?

15.9 **Where will the records pertaining to this research be stored? (give the actual physical location of the paper records i.e building name and room number); and/or the secure network drive where the data is being stored.**
Paper records will be stored in the PI's office (BG3-39), MHS Main Campus - in locked cabinet, in a locked office . Electronic records containing PHI will be stored in RedCap. De-identified electronic records will be stored on a secure, MHS network drive (Dr,. Krishnan's research folder on G: Drive).

State the exact physical location of paper files and the network drive for electronic files.

15.10 **How will these records be secured (we are refering to both paper records and electronic records)? Examples for electronic records (i.e. secure drive, password protected documents, encrypted jump drive). Examples for paper records, must be double locked (i.e. locked office and locked file cabinet or a locked file box inside a locked cabinet).**
Paper records will be stored in the PI's office (BG3-39), MHS Main Campus - in locked cabinet, in a locked office . Electronic records containing PHI will be stored in RedCap. De-identified electronic records will be stored on a secure, MHS network drive (Dr,. Krishnan's research folder on G: Drive).

i.e. locked cabinet, locked room.

15.11 **Who will have access to the data?**
Only study staff will have access to the data.

Please Note: All study documents must be retained for a minimum of four years after study completion (even when no subjects have been enrolled), twenty-two years if study involves children or pregnant women. Records for device studies must not be assigned a destruction date until the FDA approval status is determined, at which point records will be retained according to the scheme above (minimum of four or twenty-two years as appropriate). Under HIPAA regulations you must keep a record of all medical records where you looked at or recorded PHI (without a HIPAA Authorization) for 6 years (i.e. prep for research).

MHS Record Retention Policy VII-4

Give name and title exclude study staff who are MHS employees.

15.12 **How long will you keep the records pertaining to this research? Where will these records be stored after the study has been completed?**
Study records will be kept for six years after study's completion. Electronic Records will be stored in RedCap and on a secure MHS network drive (G Drive).

Check the MHS Record retention policy for guidance.

Paper records will be stored in the Dr. Krishnan's office (BG3-39), metro main campus.

You must have a plan for data destruction.

15.13

Where, when, and how will the information be destroyed?
After six years, electronic records will be deleted and paper records will be destroyed per MHS policy.

*Please Note: There are EPA regulations surrounding the destruction of CDs, DVDs, Floppy discs and other portable storage media. If you want to destroy these types of media please contact Ron Wallace in Environmental Services at 778-4776.

View: 15-01 Data Security II

15.1 Data Security II:

15.14 **Who (non-study staff) will have access to the records? Give name and title of individuals. Where an individual's name is not known give title i.e. monitor from CRO.**
None

List all those not study staff who will see and have access to data.

15.15 **Will data be transmitted to the sponsor?** ○ Yes ◉ **No**

Are you sending CRFs to sponsor?

15.16 **If yes, describe what data will be sent to the sponsor and the provisions that have been made for preservation of confidentiality in the transmission of data to the sponsor:**

Please describe i.e. will you be using encryption software?

15.17 **Will the data from this research project be transmitted to anyone other than the sponsor?** ○ Yes ◉ **No**

Check yes or no.

15.18 **If yes, to whom will this data be transmitted?**

Please describe organization or individual.

15.19 **Describe the data that will be sent to entities other than the sponsor and what provisions have been made for the preservation of confidentiality:**

Please describe data, and confidentiality provisions.

Not applicable

View: 16-00 Request for a Partial Waiver of HIPAA Authorization

16.00 Request For a Partial Wavier of HIPAA Authorization

An IRB, under certain circumstances, may allow researchers to forgo obtaining an authorization; this is called a waiver of authorization. A waiver of authorization may be full or partial:

- full waiver: an IRB waives the requirement for authorization for all uses of PHI for a particular research protocol (see Section 16.01 Request for a Waiver of HIPAA Authorization);
- partial waiver: an IRB waives the requirement for an authorization only for some uses of PHI for a particular research protocol. Researchers are required to obtain subjects' Research Authorizations after recruiting and enrolling subjects via a partial waiver and prior to creating or using PHI during research procedures.

Partial Waiver for Preparatory for Research Activities:
According to HHS guidance on the Privacy Rule the preparatory to research provision permits covered entities to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment. However, the provision at 45 CFR 164.512(i)(1)(ii) does not permit the researcher to remove protected health information from the covered entity's site. *As such, a researcher who is an employee or a member of the covered entity's workforce could use protected health information to contact prospective research subjects*. The preparatory research provision would allow such a researcher to identify prospective research participants for purposes of seeking their Authorization to use or disclose protected health information for a research study.

Under the preparatory to research provision, a covered entity may permit a researcher who works for that covered entity to use PHI for purposes preparatory to research. A covered entity may also permit, as a disclosure of PHI, a researcher who is not a workforce member of that covered entity to review PHI (within that covered entity) for purposes preparatory to research.

16.1 Are you requesting a Partial Waiver of HIPAA Authorization? ◉ **Yes** ○ No — Check yes or no.

Why are you requesting a Partial Waviver?

16.2 Is the purpose of the Partial Waiver Recruitment (including screening of Medical Records)? — Check yes or no.

◉ **Yes** ○ No

Is the purpose of the Partial Waiver to request access to PHI for Non-MetroHealth personnel?

○ Yes ◉ **No**

16.3 Will the use of Protected Health Information (PHI) involve more than minimal risk to the privacy of the patients? — Check yes or no.

○ Yes ◉ **No**

16.4 The IRB as part of it's review of this request must have certain reassurances that Patient Privacy will be protected, please respond to the following questions true or false.

Check true or false.

1.) The PHI will be used solely to facilitate the research protocol as an aid to study recruitment or to expand the research study. The waiver would allow identification of prospective research participants for the purpose of seeking authorization to use or disclose PHI for a research study. Essentially, PHI will be used to identify and contact potential research participants. Only contact and screening information (race, age, medications, diagnosis, and primary physician) will be recorded, and no information will leave the premises of MetroHealth Medical Center. The information will not be disclosed outside the research group for this study. ◉ **True** ○ False

2.) Information about potential subjects who are not interested in participating will be destroyed after the patient declines enrollment. The information of patients choosing to participate will be further used to schedule an appointment. As soon as the research staff sees the participant, a full authorization will be obtained to collect, use and disclose PHI for the remainder of the study. ○ True ◉ **False**

3.) The PHI will not be reused or disclosed. Because the PHI belongs to individuals who are not yet in the study, oversight provisions do not apply. After subjects are formally enrolled, an authorization will be in effect and the waiver will no longer apply. ○ True ◉ **False**

16.5 If you did not answer true to all three parts of question 16.4 please explain:
Patients who are not interested in participating in the study will not fill the study questionnaires and their date will not retained.

A full HIPAA waiver is also being requested for this study.

Please explain your response to any statement where you have entered false.

16.6 Please give a detailed explanation as to why this research activity cannot be practicably conducted without a Partial Waiver or without access to PHI:
PHI is required to identify patients who will be starting pulmonary rehabilitation. Once the patients are identified, the questionnaires/ surveys including Pittsburgh sleep quality index, berlin questionnaire, Epworth sleepiness scale, Hospital anxiety and depression scale, insomnia severity index (ISI) Short form health survey-36 (SF-36) for cardiac patients and COPD assessment test (for COPD patients) will be mailed to the patients or sent through MyChart with a non-return memo cover sheet. Participation in the study is voluntary.

Example: our study population has xxx disease and we rely on the EMR information to identify and contact potential subjects.

16.7 Who will have access to PHI? Please list below:

Add the names of persons who will have access to PHI.

Name	Employer	Department	Employer Name
Charles Ebersbacher	MetroHealth	Medicine	The MetroHealth System
Faiza Khalid	Metrohealth	Pulmonary and critical care medicine	The MetroHealth System
Vidya Krishnan	MHMC	Medicine	The MetroHealth System

16.8 Are you or anyone who assists you Non-MetroHealth Personnel? ○ Yes ◉ **No**

Check yes or no.

**Note all Non-MetroHealth Personnel have to go through employee orientation, have a security clearance and Epic training before they can access the MetroHealth EMR. Also all all Non-MetroHealth Personnel must work under the control of a member of the MetroHealth Staff.*

If you filed a Prep for research form with IT and RABO please attach it here.

If you have previously completed an MHS **Prep for Research form** add that form here:

Name	Version
There are no items to display	

Partial Wavier Memos completed prior to 11/26/2010 will populate here.

Old Memos Requesting Partial Waivers (prior to 11/26/2010):

There are no items to display

View: 16-01 Request for a HIPAA Waiver of Authorization

16.1 Request For a HIPAA Waiver of Authorization:

16.9 **Are you requesting a Waiver of HIPAA Authorization?**

Check yes or no.

Yes

Check one, if you check no then hit continue and go to the next page.

If you are requesting a Waiver In order for the IRB to Grant a Waiver you must answer questions 16.10-16.16

16.10 **Disclosure of Protected Health Information (PHI) will not involve more than minimal risk to the privacy of the patients/subjects:**

Check true or false.

True

16.11	**What is the plan to protect patient/subject identifiers from improper use and disclosure?** A unique identifier will be used on the data collection form. Only the PI and co-investigators will have access to the key linking the unique identifier to patient/subject names (which will be saved in REDCap).	i.e. This unique identifier will be used on the data collection form. Only the PI will have access to the key linking the unique identifier to patient/subject names.
16.12	**What is the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research?** The unique identifier key will be retained in Red Cap and will be destroyed two years after the study ends.	i.e. The unique identifier key will be retained in Red Cap and will be destroyed two years after the study ends.
16.13	**Will PHI be reused or disclosed to others:** No	Check yes or no.
16.14	**Please complete the following: Data will only be used to analyze...** Data will only be used to analyze the effect of pulmonary rehabilitation on sleep, to determine if the beneficial effects of pulmonary rehabilitation last 3 months after completion of the program and screen patients for sleep apnea and to screen patients for sleep apnea.	i.e. Data will only be used to analyze...
16.15	**Describe why this research can not be conducted without a waiver:** To obtain HIPAA Authorization from these individuals would be a greater risk to their loss of privacy for this minimal risk study.	i.e because many of the subjects who participate in this treatment are dead or have transferred to other treatment modalities, or are transient. To obtain HIPAA Authorization from these individuals would be a greater risk to their loss of privacy.
16.16	**Describe why this research could not be conducted without access to and use of PHI:** The chart review will be necessary to identify type/severity of lung disease, prior diagnosis of sleep disorders and treatments, and to track successful completion of pulmonary rehabilitation.	i.e. It would not be possible to determine linkages between .....and clinical outcomes without the use of PHI.

View: 16-02 HIPAA II

16.2 HIPAA II:

16.11		*Check all that apply, your answers will help the IRB to determine if your data is a limited data set.*

Which of the following identifiers about subjects will be collected for this study?

Name
3. Address - Street
4. Address - Town or City
5. Address - State
6. Address - Zip Code
8. Names or Initials
16. Medical record or prescription numbers
17. References to age 90 or older or references to dates (including years) indicative of age 90 or older
21. Dates (except year) related to an individual (birth date, admission date, discharge date, date of death)

*These Questions deal with the collection of data and data use agreements. If you are **not** receiving data or sending data out to another entity this does not apply to you. If you have a signed contract with a sponsor or are in a cooperative group that has a signed agreement with MHS this does not apply to you. Data use agreements specify the conditions under which data can be shared between MHS and other organizations or individuals.*

16.12 If you have selected only numbers 4, 5, 6, or 22 in question number 16.11 your research is considered to use a limited data set. If either of the following conditions apply, you will need to obtain a Data Use Agreement and complete a waiver of authorization or obtain a HIPAA authorization from the subjects. (check one):

Name
There are no items to display

Check one, please read carefully if you are not receiving data or sending data out to another entity this does not apply to you, move on to 16.14. If you have a contract with a sponsor or you are in a cooperative group that has a signed agreement with MHS this does not apply to you. In all other cases please contact the MHS Legal Department with questions about data use agreements.

16.13 Attach a copy of the Data Use Agreement:

Attach Data Use Agreement.

Name Description
There are no items to display

View: 16-03 HIPAA III

16.3 HIPAA III:

16.14 If any other unique identifying number, characteristic or code is selected, please specify:
Not applicable.

Please specify this question refers back to the list of 22 identifiers.

16.15 If a link to an identifier will be used (i.e. code numbers) is selected, please describe the coding mechanism that will be used:
A key will be made by RedCap generation

Describe the coding mechanism.

16.16 Will a certificate of Confidentiality be obtained for this study? No

Check yes or no.

16.17 If yes, please attach a copy the Certificate of Confidentiality:
Name Version
There are no items to display

Attach a copy of the Certificate of Confidentiality.

16.18 Describe how you will protect the privacy of participants. Describe specifically how you will gather information from or about them. *Please note while confidentiality concerns data, privacy concerns people. Example People may be uncomfortable answering questions about their employer in an open cubicle, so investigators may arrange for a more private location.*
Patients can decline questionnaire, as is clearly stated on non-return cover memo. Patients can complete forms in privacy of their own home. Or, we will give a private room for patients to complete survey if they so desire.

Please note while confidentiality concerns data, privacy concerns people.

View: 17-00 Waiver of Informed Consent

17.0 Request for a Waiver or Alteration of Informed Consent:

17.1 Are you requesting a Waiver of Consent [45 CFR 46.116(d)] OR a Waiver of Documentation of Consent [45 CFR 46.117 (c)].
Yes

Answer yes or no.

If no hit continue button and you will go to the next page.

If yes please Note:

Note: Waivers of consent are not applicable if the research is subject to FDA regulations, except the following.

FDA Exception from general requirements:

1. Emergency Ues: Waivers of Informed Consent in FDA-regulated studies are permissible in case of life-threatening situations, inability to communicate, not sufficient time and no alternative method, even if research presents more than minimal risk [21CFR50.23];
2. Planned Emergency Research: If the study satisfies the requirements under 21CFR50.24 “Exception from Informed Consent Requirements for Emergency Research.”

17.2 **Waiver of Consent: If you are requesting a waiver of consent, please provide the justification and address each of the following points for the IRB's consideration:**

Check true or false.

This research study involves no more than minimal risk:

Note: practicably does not mean it would be inconvenient.

The waiver will not adversely affect the rights and welfare of the subjects:

This research could not practicably be carried out without a waiver:

Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

○ **Yes** ○ **No**

17.3 **Please explain your answers to the above questions (You must provide the IRB with enough information to make a decision):**

Please explain in detail.

An IRB may **waive the requirement to obtain a *signed* consent form** for some or all subjects if it finds either of the conditions below. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

17.4

Check true or false.

(1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; OR False

Check yes or no.

17.5

(2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

◉ **Yes** ○ No

17.6 **If you are requesting any Alteration to the standard consent form/process (written long form consent is the standard) please provide a detailed explanation or plan.**

Example of an alteration: verbal consent.

A non-return cover memo will be included with the study questionnaires given to patients.

View: 17-01 Informed Consent Process I

17.1 Informed Consent Process I:

17.7 **Who will be approached to obtain consent/assent:**

Check all that apply.

Consent Method

Subjects will receive a complete explanation of the study and be asked to consent verbally. Subjects will receive a written summary of the research. Subjects will not be asked to sign a consent form.

Idendtify all Staff obtaining consent on page 1 question 1.4 by selecting the corresponding role.

17.8 **Subject Comprehension: What measures will be taken to ensure that subjects fully understand the nature of their involvement in the research?**

Please give brief explaination.

Note to Investigator:

To address issues of comprehension on the part of the participant or representative, and who is involved in obtaining consent, the answers to following questions should be addressed:

1.) ***Once a potential participant is identified, what process is followed to inform the subject of the study prior to obtaining a signature on the informed consent form?***

a. ***Who introduces the study to the potential subject?***

b. ***Who reviews the informed consent document in depth?***

c. ***Do you require the potential participant to have another person present during the presentation of the study?***

2.) Who answers the questions presented by the potential participant and/or family?

3.) What method is used to determine if the potential participant fully understands the study, what is required from them, risk and benefits, and their rights as a participant?

4.) Is the principal investigator usually present during the presentation of the informed consent?

1. Patient will be given a non-return cover memo detailing the study. If they agree to participate, they will complete the questionnaire and return it to the pulmonary rehabilitation staff.
a. A packet will be mailed to the patient's home, including the non-return cover memo explaining the study and the study questionnaires. MyChart will also be used to introduce potential subjects to the study.
b. The potential subject will read the non-return cover memo and complete questionnaires if they agree to participate.
c. NO
2. PI - Dr. Krishnan (listed on non-return cover memo)
3. Patient will read non-return cover memo and will complete questionnaires if they agree to participate.
4. NO

17.9 **Capacity to Consent: How will capacity to consent be assessed?** ***This question is to be addressed for all subjects not just those with limited decision making capacity. Identify who will make this assessment? Suggested language....all subjects will be awake, alert and oriented, be able to read etc. It is important to address issues like ability to read and understand information in the consent.***

How will you determine capacity to consent?

Patients will be awake and alert, should be able to read and not have any intellectual or cognitive disability.

17.10 **Attach a description of the Consent Process: Explain the process of obtaining consent from subjects. Under what settings and conditions will consent be obtained? What will be the timing/waiting period? What measures will be taken to ensure that subjects will make decisions independently?** *Note to Investigator: The "informed consent process" should include sufficient time for the participant to review and consider participating with the assistance of family members, research partners or representative if necessary. Other items to consider regarding time / waiting periods are: Is the potential participant given a copy of the consent form to read prior to the discussion of the study? Is it presented in person or mailed (where they can review it in the privacy of their own home)? How much time elapses between the presentation of the study and informed consent form and the actual signing of the form? The answers to these questions will ensure the PI has considered this component of the process and will*

Attach a plan for consenting subjects. This must give detail about the consent process.

reassure the IRB that the PI is allowing adequate time for the participant to make an informed decision and minimize the possibility of coercion or undue influence.

Name	Description
Informed consent.doc | History	

17.11 Parental Permission and Youth Assent: Complete this question only if enrolling minors. How will parental permission and youth assent (if applicable) be obtained?

Give details of assent process and assent form.

View: 17-02 Informed Consent Process II

17.2 Informed Consent Process II:

17.12 What method will be used to document the consent process (i.e. a note in EPIC)? <u>Not</u> how you will get consent only how you will document consent has been obtained, i.e chart note, note in study file.

i.e chart note, note in study file.

A note in the study file will be made to document consent.

17.13 What type of Informed Consent will be used in this study? (check all that apply):

Check all that apply

Consent Type	
Non-Return Cover Memo	*A non-return cover memo applies to a study in which you are sending out a questionnaire with a memo or letter that informs participants about the study but does not need to be signed and returned. If they complete and return the questionnaire they have given consent.*

17.14 If other, please specify:

If other, please give specifics.

****Attach all consent forms (Informed Consent, Genetic Consent and HIPAA) here:****

17.15 Please attach a copy of each Informed Consent form(s) and HIPAA Authorization you are using for this study:

Attach Consent form(s) and HIPAA Authorization here

Name	Version
Non-return cover memo for pulmonary rehab and sleep.docx	0.11

17.16 Will non-English speaking subjects be enrolled?

Check one

○ Yes ◉ No Clear

Please give the IRB an explanation as to why non-English speaking subjects will not be enrolled.

If the answer to 17.17 is no we will not be enrolling non-English speaking subjects then tell the IRB why not?

we need English speakers for the survey. Non-English translation of all of the surveys are not available or validated at this time.

17.17 If non-English speaking subjects will be enrolled please provide information about the person(s) obtaining consent (what language they will speak)and how you will deal with written translation(s):

Provide information about translating consents and having interpertative services available for consent.

Not applicable

View: 25-00 Surveys/Questionnaires

25.0 Surveys/Questionnaires:

25.1 Does this study involve Surveys/Questionnaires? Yes

Answer yes or no.

If you answer no and hit continue you will go to the next section.

25.2 Please attach all questionnaires and/or surveys to be used in this study:

Attach survey(s)/questionnaire(s).

Name	Version
Berlin questionnaire | History	0.01
CAT (USA English).pdf | History	0.01
Epworth sleepiness scale | History	0.01
Hospital_Anxiety_and_Depression_Scale (1)(1).pdf | History	0.01
InsomniaSeverityIndex_ISI.pdf | History	0.01
PSQI | History	0.01
SF-36_website_PDF.pdf | History	0.01

25.3 Idendtify all Staff conducting Surveys on page 1 question 1.4 by selecting the correct role.

View: 26-00 Deception

26.0 Deception:

Deception is a research methodology. When deception is used in research the subject is not told, or is misled, about the true purpose of the research, such as in certain studies of group processes, contextual influences on cognition, etc.

26.1 Does this study involve the use of deception as a study design method for the research?
No

If you checked no then hit the continue button and you will be taken to the next page.

Deception is defined as intentionally misleading or withholding information about the nature of the experiment.

26.2 Describe in detail the nature of the deception and explain why this is necessary for the research:

Please describe the nature of the deception.

26.3 State how, when and by whom the research subjects will be debriefed:

Briefly describe your plan to debrief subjects.

View: 27-00 Additional Documents

27.0 Additional Documents:

27.1 Are there any additional study documents you wish to attach to this application?
Name Version
There are no items to display

Attach any additional study documents i.e protocols supplied by sponsor.

View: The End

To Finalize this application you must do two things:

1.) As a final step you should click on Hide/Show Errors on the top of this page. If there are any required fields in the Application you have omitted they will show up in red. If you click on each item you will be taken to that page of the application so you can complete the question.

Note: Unless all named Co-investigators have agreed to participate you will not be able to submit your study. Co-Investigators have to press the Co-Investigators agree to participate button. You can send them an email message tellng them to do this by pressing

Notify Co-Investigators of Need to Agree to Participate. The minute you have selected your Co-Investigators you can press this button it is not advisable to wait until you have completed the application as it may hold up your submission.

When all error messages are gone then...

2.) Click Finish

Please click on the "Finish" button to finalize and exit the Study application. Doing so will **NOT** submit the application for review.

3.) The PI must press the Submit Study button (when they are ready to submit to the IRB)

Please note that a submission may only be forwarded to the IRB by the Principal Investigator. To do this, the Principal Investigator must push **" Submit Study"** in the blue area on the left hand side of the page under **My Activities**. Only the PI will have this button it will not be visible to any other study team members.

You can track the ongoing status of your submission by logging into the study workspace. On the top left hand side of the page in the light blue area there will be a box labeled with the **Current State** of your study.

Please contact the IRB with any questions or concerns. When calling the IRB Office Please direct your questions to the IRB staff named as the "Owner" of your study.

View: CCF Key Personnel Questions View
* **Name of Key Personnel Working on Study:** Faiza Khalid

Study Role:
Name
Co-investigator
DRA (only one)
Interviewer (Survey, Focus Group)
Obtaining Informed Consent
eIRB Notification Recipient

View: CCF Key Personnel Questions View
* **Name of Key Personnel Working on Study:** Charles Ebersbacher

Study Role:
Name
Co-investigator
Obtaining Informed Consent