DREXEL UNIVERSITY Office of Research

Office of Research
Human Research Protection Program
Drexel University
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Approval for a Project Involving Human Subjects Research that Does Not Require Continuing Review

Date: June 24, 2019

Protocol Number:	1905007203
Principal Investigator:	Catherine O'Hayer, PhD
Review Type:	Expedited
Review Date:	June 13, 2019
Approved On:	June 24, 2019
Committee:	IRB 1
Sponsor:	Boomer Esiason Foundation
Project Title:	"Acceptance and Commitment Therapy vs. Supportive Psychotherapy with Cystic Fibrosis Patients "

The IRB determined that the research meets the approval criteria set forth in (where applicable): 45 CFR 46.111, 21 CFR 56.111, and 45 CFR part 46 subparts B, C, or D.

It was also determined that the research **does not require a continuing review**. Consequently, there is no IRB approval period listed for this project.

If applicable to your study, you can access your IRB-approved, stamped consent document or consent script through Coeus. Open the Attachments tab to find the approval letter or approval packet. The stamped documents are labeled as such. **Copies of the IRB approved stamped consent document or consent script must be used in obtaining consent.**

Please note: All applicable Institutional and non-Institutional approvals must also be secured prior to study implementation. These approvals include, but are not limited to, Radiation Safety Committee ("RSC"); Institutional Biosafety Committee ("IBC"); and Conflict of Interest, ("COI"); individual departmental and external site approvals.

Finally, in conducting this research, you are obligated to submit the following:

- **Amendment requests** – **All changes to the research must be reviewed and approved by the IRB**. Changes requiring approval include, but are not limited to, changes in the design or focus of the research project, revisions to the information sheet for participants, addition of new measures or instruments, increasing the subject number, and changes to the research funding. **Changes made to eliminate apparent immediate hazards to subjects and implemented prior to IRB approval must be promptly reported to the IRB.**

- **Reportable New Information** – Using the Reportable New Information e-form, report new information items such as those described in HRP-214 Form - Reportable New Information to the IRB **within 5 days**.

- **Final Report (Closure report)** – Submit when the study is permanently closed to enrollment, all subjects have completed all protocol related interventions and interactions, collection of private identifiable information is complete, and analysis of private identifiable information is complete. If the Principal Investigator is leaving Drexel, the study must either be formally closed or a Modification must be submitted to approve a new Principal Investigator.

For the complete list of investigator responsibilities, please see the Investigator Manual (HRP-103) and other Policies and Procedures found on the Drexel University IRB website.

Please contact the IRB at (215) 762-3944 or HRPP@drexel.edu if you have any questions.

Drexel University
Consent to Take Part
In a Research Study

1. Title of research study: *Acceptance and Commitment Therapy with Cystic Fibrosis Patients*

2. Researchers: *C. Virginia O'Hayer, Ph.D., Patrick Smith, Ph.D., Christopher Drescher, Ph.D. & Michael Stephen, MD*

3. Why you are being invited to take part in a research study

We invite you to take part in a research study because you have cystic fibrosis.

4. Concise Summary of Key Information:

We are performing this research to find out if teaching ways to help people manage anxiety and depression, affect how they feel and how they take their cystic fibrosis medications. The consent is being sought for research and participation in this study is voluntary. If you agree to participate in this research study, you will be asked to complete a series of brief questionnaires at the time of your intake appointment. You will complete each questionnaire again after 6 appointments (i.e., about 6 weeks later), and again about 3-months after your sixth appointment. You will also be asked to complete 6 'Zoom' therapy sessions (using a webcam in your own home or on your own tablet/smartphone) of either "Acceptance and Commitment Therapy", in which you will learn new ways to manage uncomfortable experiences and feelings and to engage in positive behaviors, or to "Supportive Psychotherapy", in which you will talk about your experiences to date. We expect that you will be in this research study for 6 weeks of therapy (once a week) and will complete questionnaires 3 months after this therapy. We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include that your mood and symptoms of depression or anxiety may get better. There is minimal risk associated with this research study. You may experience uncomfortable feelings from some of the questions and/or from therapy sessions. You do not need to answer questions for the study that you are uncomfortable answering. Also, there is a small risk that your personal information may be disclosed to others. Every effort will be made to keep your personal information confidential. You may decide not to take part in the research and it will not be held against you. If you agree to take part in the research now and stop at any time it will not be held against you. If you decide to leave the research, there will be no adverse consequences. There is no cost to you and no compensation for participating in this study.

5. What you should know about a research study

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

6. Who can I talk to about this research study?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Dr. O'Hayer's office (267-507-6569).

If you are experiencing suicidal thoughts, urges, or actions during your participation in the study, you can contact Dr. O'Hayer directly at 919-943-6738.

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (215) 762-3944 or email HRPP@drexel.edu for any of the following:

Your questions, concerns, or complaints are not being answered by the research team.
You cannot reach the research team.
You want to talk to someone besides the research team. You have questions about your rights as a research subject.
You want to get information or provide input about this research.

7. Why are we doing this research?

The purpose of this study is to find out if teaching ways to help people manage anxiety and depression, affect how they feel and how they take their cystic fibrosis medications.

8. How long will the research last?

We expect that you will be in this research study for 6 weeks of therapy (once a week) and to complete some questionnaires 3 months after this therapy.

9. How many people will be studied?

We expect about 210 people will be in this research study. Participants will be recruited by on-site representatives at off sites and by Research Coordinator Chelsi Nurse at local sites.

10. What happens if I say yes, I want to be in this research?

You will be asked to complete a series of brief questionnaires at the time of your intake appointment. These questionnaires will ask you about: 1) how often you experience different thoughts and feelings, including some related to having cystic fibrosis; 2) how often you take your cystic fibrosis medications; 3) your coping style, including how long you persist in thinking about something that has happened to you; You will complete each questionnaire again after 6 appointments (i.e., about 6 weeks later), and again about 3-months after your sixth appointment.

These questionnaires take about 45 minutes to complete. You will also be asked to complete 6 'Zoom' therapy sessions (using a webcam in your own home or on your own tablet/smartphone) of either "Acceptance and Commitment Therapy", in which you will learn new ways to manage uncomfortable experiences and feelings (e.g., depression, anxiety) and to engage in positive behaviors, or to "Supportive Psychotherapy", in which you will talk about your experiences to date. The type of therapy that you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given each therapy. Audio and video recordings will be taken during each 'Zoom' therapy session. Recordings will be kept on password encrypted usb drives and stored in a locked office only accessible to the principle investigator and adherence coder.

Finally, we hope to learn whether these therapies affect how often you take your cystic fibrosis medications, and how this affects your health and wellbeing. To study this, we will review information from your medical chart such as the number of appointments that you keep, the number of appointments that you miss, your pulmonary function tests, whether you go to the hospital or see your doctor for any extra visits, and the presence of any symptoms of depression or anxiety.

11. What are my responsibilities if I take part in this research?

If you take part in this research, it is very important that you:

- Follow your physician's or researcher's instructions.
- Tell your study physician or researcher right away if you have a complication or injury.
- Attend all 6 therapy sessions and the 3-month follow-up session.

12. What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you.

13. What happens if I say yes, but I change my mind later?

If you agree to take part in the research now and stop at any time it will not

be held against you. If you decide to leave the research, there will be no adverse consequences. If you decide to leave the research, contact your therapist or Dr. O'Hayer.

14. Is there any way being in this study could be bad for me?

You may experience uncomfortable feelings from some of the questions and/or from therapy sessions. You do not need to answer questions for the study that you are uncomfortable answering. Also, there is a small risk that your personal information may be disclosed to others. Every effort will be made to keep your personal information confidential. If you are experiencing suicidal thoughts, urges, or actions during your participation in the study, you can contact Dr. O'Hayer directly at 919-943-6738.

15. Do I have to pay for anything while I am on this study?

There is no cost to you for participating in this study.

16. Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include that your mood and symptoms of depression or anxiety may get better.

17. What happens to the information we collect?

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

18. What else do I need to know?

This study is being done by Drexel University.

Duke University Medical Center has IRB in progress.

Augusta University Medical Center and University of Pittsburg have ceded IRB to Drexel.

Authorization to Use and Disclose Protected Health Information

Federal law provides additional protections of your personal information that are described here.

A. *Individually Identifiable Health Information That Will Be Collected*

The following personal health information about you will be collected and used during the research study and may be given out to others:

- Your name, address, telephone number, and date of birth.
- Personal medical history.
- Scores on a depression scale (the Beck Depression Inventory-II), an anxiety scale (Beck Anxiety Inventory), Cystic Fibrosis Questionnaire, a scale on coping with stress, and cystic fibrosis medication adherence.
- Information from pulmonary function tests, x-rays, physical exams and other tests or procedures described in this consent form.
- Audio and video recordings will be taken during each 'Zoom' therapy session. Recordings will be kept on password encrypted usb drives and stored in a locked office only accessible to the principle investigator and adherence coder.
- Information learned during telephone calls, surveys, questionnaires and office visits done as part of this research study. Your name, address, telephone number, date of birth;

B. *Who Will See and Use Your Health Information within Drexel University*

The researcher and other authorized individuals involved in the research study at Drexel University will see your health information during and may give out your health information during the research study. These include the researcher and the research staff, the institutional review board and their staff, legal counsel, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the research study or make sure it is being done properly. Your health information may be disclosed or transmitted electronically.

C. *Who Else May See and Use your Health Information*

Other persons and organizations outside of Drexel University may see and use your health information during this research study.

Governmental entities that have the right to see or review your health information, such as The Office for Human Research Protections.

Doctors and staff at the hospital where this research study will take place.

If your health information is given to someone not required by law to keep it

confidential, then that information may no longer be protected, and may be used or given out without your permission.

D. Why your health information will be used and given out

Your health information will be used and given out to carry out the research study and to evaluate the results of the study.

Your information may also be used to meet the reporting requirements of governmental agencies.

E. If you do not want to give authorization to use your health information

You do not have to give your authorization to use or give out your health information.
However, if you do not give authorization, you cannot participate in this research study.

F. How to cancel your authorization

At any time, you may cancel your authorization to allow your health information to be used or given out by sending a written notice to Human Research Protection at 1505 Race Street, 7th Floor Bellet Bldg, Philadelphia, Pennsylvania, 19102. If you leave this research study, no new health information about you will be gathered after you leave. However, information gathered before that date may be used or given out if it is needed for the research study or any follow-up.

G. When your authorization ends

Your authorization to use and give out health information will continue until you withdraw or cancel your authorization. After the research study is finished, your health information will be maintained in a research database. Drexel University shall not re-use or re- disclose the health information in this database for other purposes unless you give written authorization to do so. However, the Drexel University Institutional Review Board may permit other researchers to see and use your health information under adequate privacy safeguards.

H. Your right to inspect your medical and research records

You have the right to look at your medical records at any time during this research study.
However, the researcher does not have to release research information to you if it is not part of your medical record.

Signature Block for Capable Adult
Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Form Date