IRB Approval:	6/11/2019
IRB Accepted:	6/11/2019
IRB Expiration:	5/22/2020

Study Volunteer Initials _____

Lifespan Affiliate Site where research will be conducted

☒ Rhode Island Hospital
☐ Bradley Hospital
☒ The Miriam Hospital
☐ Newport Hospital
☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

2085-18
Committee #

Name of Study Volunteer _____

Acceptance and Commitment Therapy for Tobacco Cessation Initiated in a Psychiatric Partial Hospital

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study: You are being asked to take part in a research project because you are a daily smoker and a patient in the Rhode Island Hospital Adult Psychiatric Partial Hospital Program. This study tests whether a treatment, called Acceptance and Commitment Therapy, is better at helping psychiatric patients stop smoking than a usual care treatment.

We expect to enroll 40 subjects into this study. The study is sponsored by the National Institute on Drug Abuse.

2. Explanation of Procedures: If you take part in this study, you will complete two study visits while you are a patient in the Partial Hospital Program. These visits will take place in the partial hospital and will include completing study surveys and receiving counseling to help you stop smoking. Following these two visits, you may receive up to five sessions of telephone counseling over the next month. After the last counseling visit, you will complete a final, in-person visit, in Dr. Jennings's laboratory at The Miriam Hospital. During this visit you will complete study surveys and assessments, including using a carbon monoxide monitor to measure the carbon monoxide levels in your breath. All patients in the study who do not have a medical reason not to take the nicotine patch will have the option of receiving 4 weeks of the nicotine patch at the first study visit, and an additional 4-week supply of the nicotine patch at the follow-up visit.

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At the beginning of the study, you will be randomly assigned to one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group.

The two groups are the Acceptance and Commitment Therapy group (ACT) and the Enhanced Usual Care group (EUC). The ACT group will receive in-person and telephone counseling delivered by the study counselors based on the principles of Acceptance and Commitment Therapy. The two key components of ACT are: (1) acceptance of unpleasant thoughts, feelings or sensations, and (2) commitment to values-guided action despite discomfort. The EUC group will receive two in-person visits focusing on setting a plan for quitting or reducing smoking. After the second visit, participants will be electronically referred to the RI Tobacco Quitline (Quitworks) for telephone counseling. Sessions with the study staff in each condition will be audiotaped for supervision of study staff. Audiotapes will be maintained until the end of data collection and analysis of study data. The RI Tobacco Quitline will send the study a report of whether you used their telephone counseling. We will ask you during the follow-up visit about your use of the nicotine patch.

Compensation. You will be paid $40 total for participation in this study. You will receive $20 to complete the first study visit and $20 to complete the follow-up visit.

Costs for participating in this study

Some of the services you will receive are being performed only because you are participating in this research study. Examples of these 'research only' services include study counseling and carbon monoxide testing. Those services will be paid for by the study and will not be billed to you or your health insurance company. For example, nicotine patches and stop smoking counseling will be provided to you at no cost.

Other services you will receive during this research study are considered "routine clinical services" that you would have received even if you were not in the research study. Examples are the therapy, medications, and assessments you receive as part of your treatment in the partial hospital. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

Contact Information:

If you have any questions or concerns about your participation in the study, or if you are having a side effect from the nicotine patch, you can call the study principal investigator, **Ernestine Jennings, Ph.D., at (401) 793-8266**.

3. Discomforts and Risks

We do not expect the stop smoking counseling to cause you discomfort. It is possible, but unlikely, that filling out surveys about your smoking and psychiatric symptoms or talking to a counselor would make you feel uncomfortable. All research staff are professionals and all information will be kept confidential.

The discomforts of quitting or reducing smoking include withdrawal symptoms such as mood swings, anxiety, irritability, decreased concentration, restlessness, excessive hunger, and trouble

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sleeping. These symptoms not dangerous and usually only last about one to two weeks after quitting/reducing. Use of the nicotine patch may result in side effects. The most common side effects of nicotine patch are skin irritation at the site on which the patch is applied, trouble sleeping, disturbed or vivid dreams, and nausea. In rare cases, you could experience an allergic reaction to the patch. Allergic reactions could consist of rash, hives, and/or swelling of the mouth/face/lips/tongue. If you experience any side effects that concern you, discontinue using these products and contact your primary care physician. Visit a local emergency room (ER) or call 911 if you are experiencing a medical emergency and need immediate treatment.

It is possible that if you stop smoking, the doses of your psychiatric medicine will need to be adjusted. To participate in this study, you must agree to allow study staff to inform your primary care provider and your psychiatric providers about your participation in the study and that you may have been given the nicotine patch.

You have my permission to contact my partial hospital psychiatrist and inform him/her of my study participation:

Psychiatrist name_____

Participant signature_____

You have my permission to contact my primary care provider and inform him/her of my study participation.

Primary care provider name_____

Participant signature_____
□Not applicable, I do not have a primary care provider

You have my permission to contact my outpatient psychiatrist and inform him/her of my study participation.

Psychiatrist name_____

Participant signature_____
□Not applicable, I do not have an outpatient psychiatrist

If you report to our study staff that you are considering harming yourself or someone else, we have a duty to keep you and others safe. If we believe you are at risk of harming yourself or others, you will receive a call from the study principal investigator, Ernestine Jennings, Ph.D., or a covering mental health provider. If the risk is severe, we may inform your psychiatric providers, or call an ambulance to transport you to the nearest emergency room for further evaluation.

<u>The nicotine patch is not FDA approved for use with pregnant women or while breast feeding.</u>
Women will be asked at the beginning of the study if they are pregnant or nursing. Women of childbearing potential will be asked to take a pregnancy test before receiving the nicotine patch. If you become pregnant during your participation in the study, discontinue using the nicotine patch.

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4. Benefits

You may or may not benefit from participating in this study.
You may reduce or quit smoking, which may improve your health. The knowledge gained from the study may lead to improvements in treatments for quitting smoking.

5. Alternative Therapies

If you decline to participate in this study, alternative counseling programs are available to help you quit smoking at other treatment centers and private clinics, and from the RI Smokers' Quitline at 1-800-QUIT-NOW. The nicotine patch is available over-the-counter. Other types of medications to help you quit smoking are available over the counter and by prescription from a physician.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit the study at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible.

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study please tell the head researcher, Ernestine Jennings, Ph.D.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

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Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff
- The Rhode Island Tobacco Quitline
- Hennepin Healthcare Research Institute (an institution collaborating on the study)
- The study sponsor: the National Institute on Drug Abuse
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- Your primary care provider and your psychiatric prescribers
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights; European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health

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care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

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

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document expires on 5/22/2020.
DO NOT sign this document after this expiration date.

The Researcher is required to provide a copy of this consent to you.

Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

Signature of witness (required if consent is presented orally or at the request of the IRB) Date

Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.