Memorial Sloan-Kettering Cancer Center
IRB Protocol#: 14-062 A (12)

INFORMED CONSENT FOR CLINICAL RESEARCH

Quit IT: Preliminary Testing of a Web-based, 3D Coping Skills Game to Increase Quitting Self-Efficacy for Maintaining Smoking Abstinence following Hospitalization

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

A member of the study staff will explain the research study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your family and friends.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

Why is this study being done?

The purpose of this study is to develop and test a web-based game called Quit It that is designed to help smokers who have quit smoking cope with any smoking urges they may have. The purpose of the game is to help people quit and stop people from smoking again.

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

How was I selected to be in this study?

You are being asked to take part in this study because you have recently been diagnosed with cancer or have a mass suspicious of cancer and are planning to receive in-patient treatment at Memorial Sloan-Kettering Cancer Center (MSKCC).

How many people will take part in the study?

About 66 people will take part in this study at MSKCC.

What will happen if I take part in this research study?

Before you begin the study …

We reviewed your medical record to verify that you may be eligible to participate in this study. We will also describe the study to you and answer any questions you may have.

During the study…

If you choose to take part, then you will be asked to:

- Complete a baseline survey that takes about 30 minutes. This survey asks about
    - your age and background information;
    - your use of tobacco;
    - your beliefs about tobacco use and cancer;
    - your prior quit smoking experiences;
    - your mood

- We will then randomly assign you to one of the study groups. This means that you will have a 50/50 chance (like flipping a coin) of being in either group.

    - If you are in **Group 1**, you will receive usual care, which consists of four (face-to-face or telephone) counseling sessions with a trained nurse who has expertise in helping cancer patients quit smoking. This is the same as the treatment an MSK patient who enrolls in the MSK smoking cessation program would receive.
    - If you have not already completed the initial contact (by phone or face to face) with a tobacco treatment counselor, the first session will be about 60 minutes and will take place shortly after you consent to this study. Your counselor will provide information about smoking cessation medication and help you choose a quit smoking date if you have not already quit.
    - The next three counseling sessions will occur within three months after your hospital discharge. Each counseling call will last about 15 minutes and will provide additional support for coping with urges to smoke.
    - If for any reason a counseling session occurs significantly behind schedule, it may be combined with the next scheduled session, You may also call the cessation counselor on your own if you have any questions or concerns about your study medication or quitting smoking.

    - If you are in **Group 2**, you will receive the same counseling program described for Group 1 above. In addition, once admitted to the hospital, you will be trained by our study staff on use of a web-based game called Quit It. You will watch a tutorial video that is about 4 minutes long with the study staff. You will then be asked a few questions about what you saw in the tutorial to make sure you understand the Quit It game. In the Quit It game, you control and make decisions for four fictional characters in a series of episodes. Each episode lasts about 15 minutes. You will be presented with a situation where it is difficult to avoid smoking. Your goal in this game is to keep from smoking. The events are modeled after real-world situations in which smokers are often tempted to smoke. You must evaluate the situations and choose the best coping strategies from a list of options. You will then receive feedback on the degree to which those strategies were helpful.

    - You will be asked to play the game during your hospitalization for up to 1 month once you start the game. You will be encouraged to play Quit It at least 3-4 ("Episodes") sessions per week for one month. You will receive 4 weekly email or letter reminders to play the game

One month after you start the game you will no longer have access to it. An iPad will be loaned to you for one month. At the end of your 1 month of game play we will provide shipping materials for you to send it back to us at our cost. Study staff can install the QuitIT game on your personal iPad if you prefer to use your own.

- We will be able to see the number and type of temptations and coping scenarios used and your final score. After you play the game for 30 minutes total, the game system will ask you a few additional questions. The questions will be about whether you found the game helpful and how you feel about quitting. The questions will take about five minutes to complete.
- At approximately 1 month post-hospital discharge you may be asked to participate in a 20 minute telephone interview. Participation in the interview is optional. It will be conducted by members of the MSKCC study staff. It will take place over the phone at a time that's convenient for you. We will ask you what you think about the game intervention. We want to know if you think the game could help people like yourself cope with urges to smoke. The phone interview will be audio recorded but your name will not be linked to it.

For both groups, a member of the research team will contact you at additional times as outlined below. This is separate from the counseling that you will receive that was described before.

o At approximately 1 and 3 months post-hospital discharge, a member of the research team will contact you by mail, email and/or by phone. You will be asked to complete a survey that includes questions about your quitting progress, symptoms of nicotine withdrawal, medication use and satisfaction with the counseling received. The questions will be similar to the ones that you answered when you enrolled in the study. For those in Group2 who played the Quit It game, we will ask you to rate the game's helpfulness, and provide any additional feedback you may have. Each survey will take about 20 minutes to complete. We will also send you a reminder letter and copy of each survey approximately two weeks before it is due. We will send you additional copies of the survey on the day that it is due and two weeks after it is due.

o The questionnaires can be completed over the phone at a time that is convenient for you. If you prefer, we can mail you the survey and you may complete the survey on paper and return it to us in a pre-addressed, stamped envelope. Or we can send you an email with instructions for completing the questionnaire online. You will be able to access the survey from any computer or tablet. The answers that you give on the surveys will be stored on a secure password protected database.

o At about 3 months post-hospital discharge, if you tell us that you have not smoked for at least seven days, you will be asked to provide a saliva sample or an expired air carbon monoxide sample. These samples will be collected either in-person or through the mail. This will allow us to confirm that you have not recently been exposed to tobacco smoke.

After the study…

We will review your medical chart to get information on your medical condition, such as length of hospital stay, treatment received and complications. We hope that collecting this information will allow us to better understand certain health events that may effect your smoking status.

After you have finished the study, it is possible that you may be called to clarify a comment or answer you have given.

How long will I be in the study?

You will be asked to take part in the study for about 3 months.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?

There are no physical risks involved with this study. It is possible that some of the questions you will be asked or just playing the Quit It game could make you feel uncomfortable. You may decline to answer any of the questions asked. Please tell the study doctor or study staff if you feel uncomfortable or upset during your participation in this study.

Are there benefits to taking part in the study?

You will not benefit directly from the study. However, your participation will help researchers develop a game to help smokers quit and remain non-smokers.

Will I receive the results from the study?

We will be happy to share the overall results of the study with you when they are available. Please let us know if you wish to receive a report by contacting the research staff at (646) 888-0088.

Do I have to take part in this study?

The choice to take part in this study or not is yours. Make your choice based on what we have explained to you and what you have read about the study.

Your other choices may include:

- Getting our routine tobacco cessation counseling
- Getting tobacco cessation counseling outside MSKCC
- Getting no tobacco cessation treatment (quit on your own)

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. 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.

What are the costs of taking part in this study?

You and/or your health plan/insurance company will need to pay for all of the routine costs of treating your cancer.

You will not be charged for the smoking cessation counseling provided.

You will receive $50 cash or money order for the baseline survey and $25 cash or money order for each follow-up survey that you complete, for a total of up to $100.

If you choose to participate in a telephone interview you will receive an additional $10 cash or money order for your time.

You will receive $20 cash or money order for providing a saliva or CO sample.

What happens if I am injured because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for the medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor Jamie Ostroff at 646 888 0041 and/or your study contact Michelle Iocolano at 646 888 0088 if you have any questions.

Any hospital that does research on people has an institutional review board (IRB). This board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSKCC has reviewed this study.

For a non-physician whom you may call for more information about the consent process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

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RESEARCH AUTHORIZATION

Research Participant Name: _____

Research Participant MRN :_____

Information about you and your health is personal. It is "Protected Health Information." We cannot use any of your health information for research unless you tell us that we can. If you take part in this research, the people or organizations that can look at your information are listed below. You will have to sign this form to tell us we have your permission to share your protected health information.

The following persons and/or organizations may use or disclose your information for purposes related to this research:

- The people in charge of the study and their assistants and support staff.

The following persons and/or organizations may look at your information for purposes related to this research:

- Members and staff of the hospital's Office of Clinical Research, Computing Resource Group that manages research databases, Data Safety Monitoring Board, and the Quality Assurance Committee.
- Members and staff of the hospital's Institutional Review Board and Privacy Board.
- The National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, and other agencies responsible for oversight.
- The following sponsor(s) of this research: Memorial Sloan Kettering Cancer Center
- Others: Muzzylane Co who developed the QuitIT game, Paul Krebs PhD at New York University who helped design the game and will participate in running the study, and the Clinical and Translational Sciences Center which hosts REDCap for data entry and storage

The following information will be used and/or disclosed for this research:

- Your entire research record.
- HIV-related information. This includes any information showing that you had an HIV-related test, have HIV infection, HIV-related illnesses or AIDS, or any

information that could mean you might have been exposed to HIV. New York State requires us to obtain this consent.

- HIV-related information collected during this study if you choose to disclose it when talking to any of the staff.
- Your medical records from the hospital
- The following information: Questionnaires and Quit It game

If you sign this form, it means you are giving us permission to share your protected health information. We can only share it with the people or organizations describe above. The purpose for the use and sharing of this information is to conduct this study. This signed form allows us to make sure that everyone who needs information related to this study can get it.

Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital.

Some of the people or organizations listed above may not be subject to privacy laws. This means they could share your information again.

You do not have to sign this form. If you do not sign it, you will not be able to take part in the study. Your health care outside the study will not be affected. The payment for your health care or your health benefits will not be affected.

You have the right to withdraw from the study at any time. If you sign this authorization form, you also the right to withdraw it at any time. If you withdraw it, we cannot use or share anymore of your research data. If the hospital has already used or shared your information, it cannot be taken back. This authorization allows us to use your information until you say we cannot use it anymore. If you want to withdraw your authorization, write to: Jamie Ostroff, PhD at the Department of Psychiatry and Behavioral Sciences, Memorial Sloan-Kettering Cancer Center.

Notice About HIV-Related Information

Once we have shared your HIV-related information, it can only be shared again if federal or state laws allow it. You have the right to ask for a list of any people who get your HIV-related information that are not listed above. There are two agencies to help protect your rights. Call them if you think you have been singled out or harmed because of HIV-related information.

- New York State Division of Human Rights (888) 392-3644
- New York City Commission of Human Rights (212) 306-7500

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Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (**LAR**). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision.

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand. ☐ **YES** ☐ **NO** ☐ **N/A (Adult or Child <7)**		
Consenting Professional's Signature		**Date:**
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		**Date:**
Participant/LAR Name (Print)		
LAR Relationship to Participant		

Witness Signature (If Required)

☐ **Non-English Speaking Participant Witness and/or Interpreter:** I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).

☐ **Other:** I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: _____

Signature of Witness: _____ Date: _____

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form.