Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study

For adults participating in interactive video arm

Title of research study: ***A prospective study showing the effect of video interactive education on medical decision making in patients on opiate replacement therapy (ORT) with a history of hepatitis C.***

Version Date: February 7, 2020

Investigator: ***Dr. Andrew Talal***

Dr. Andrew Talal and his spouse, Dr. Marianthi Markatou, are co-investigators on this study. Dr. Talal has been paid travel support and consultancy fees for speaking for the sponsor, Merck and Company, in the past.

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are at least 18 years old, and enrolled in an opiate replacement therapy program.

What should I 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 and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to determine the most effective way to give patients information regarding hepatitis C virus infection. We plan to compare the information retained by some patients who are given a brochure alone versus patients who watch an interactive video about hepatitis C.

This study is being conducted within this treatment program because other studies have shown there are a lot of people with a history of opioid use who have hepatitis C.

Permission to Take Part in a Human Research Study

How long will the research last and what will I need to do?

We expect that you will be in this research study for up to 1 month. You will be asked to fill out 3 questionnaires and then watch a 20-30 minute video. In one month you will be asked to fill out one of the questionnaires again.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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

Some of the questions on the questionnaire may make you uncomfortable. The only other potential risk in this study is a breach of confidentiality.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include learning more effective ways to educate the public about hepatitis C.

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

Your participation in this research study is voluntary. You may choose not to enroll in this study.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team a 716 888-4739. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- 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 want to get information or provide input about this research.

How many people will be studied?

We expect about 200 people in this research study.

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

After signing an informed consent, we will give you 3 questionnaires to complete. The first questionnaire will be about general information called demographics this would include information such as your age, level of education, address, how we may contact you regarding study visits, etc.

Permission to Take Part in a Human Research Study

The second questionnaire will be a short list of medical terms we would like you to read out loud.

The last questionnaire is what is known as a pretest. This will have questions about hepatitis C. This questionnaire will help us to understand how much you knew about Hepatitis C before the education session.

After the questionnaires are completed, you will watch a 20 to 30 min video about hepatitis C.

As soon as you are done watching the video we will ask you to complete the questionnaire about hepatitis C again.

Finally, in one month, we will ask to you complete the questionnaire about hepatitis C again to find out how much of the video information you remember.

All study visits will take place here at your treatment center. If you are unable to return to the treatment center in time for your one month follow up, the questionnaire can be completed over the phone

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

If you take part in this research, you will be responsible to: complete the questionnaires to the best of your ability now and in one month.

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

You can leave the research at any time it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can put a note in your file alerting the other team members of your voluntary discontinuation from the study.

Is there any way being in this study could be bad for me? (Detailed Risks)

There are no known risks associated with these procedures, but there may be some questions we ask that may be uncomfortable to answer. While you are not obligated to answer, doing so will help us to understand how certain circumstances effect the patients participating within this study, and may also assist us with designing ways to teach you about hepatitis C and other health issues.

The only other potential risk is breach of confidentiality. To mitigate this risk, all study data will be stored in a secure, password-protected database accessible by only the research team on password-protected hospital computers in locked offices.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education 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 as well as Merck pharmaceutical, the sponsor of this study.

The sponsor, monitors, auditors, and the IRB, will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Permission to Take Part in a Human Research Study

If identifiers are removed from your identifiable private information that is collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include incarceration or if you should move out of the area or discontinue as a patient at your current treatment center.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

Who is paying for this research?

This research is being supported by Merck and Company, a manufacturer of medications used to treat hepatitis C.

Will I get paid for my participation in this research?

If you agree to take part in this research study, we will pay you $20 as cash or a gift card for your time today and $20 as cash or a gift card in one month after you have completed the follow-up questionnaire. If you complete the study day 2 questionnaire over the phone, the $20 can be held for you at the treatment center, picked up at 875 Ellicott St in Buffalo, or mailed to you. If you choose to have the payment mailed to you than you are accepting the possibility of the payment getting lost in the mail.

Study day 1 questionnaire and education	$20.
Study day 2 questionnaire (one month from study day 1)	$20.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

- Information from your full medical records: Full medical history, demographics

Provide a general description of information that will be collected: age, gender, race/ethnicity, educational status, marital status, mental health history, information about substance abuse and hepatitis C status, occupational and employment status.

Permission to Take Part in a Human Research Study

B. Who is authorized to provide or collect this information?

- Principal Investigator (study doctor) or designee
- Your treatment center

C. Who is authorized to receive the information from the information providers identified in (B)?

- Principal Investigator (study doctor) or designee

D. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

- Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment or if you are otherwise lost to follow-up.
- The study Sponsor, and those working for or with the Sponsor, which may include affiliates of the Sponsor located in your country or other countries, its current or future research partners, collaborators, assignees, licensees or designees.
- The organization(s) responsible for administering this research study: Research Foundation for SUNY.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), foreign regulatory authorities, the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long will this information be kept by the Principal Investigator?

This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about you.

F. What are your rights after signing this authorization?

Permission to Take Part in a Human Research Study

You have the right to revoke this authorization at any time. If you withdraw your authorization, you will not be allowed to continue your participation in this study, and no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the study doctor(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Andrew Talal, M.D.
Clinical and Translational Research Center
875 Ellicott Street
Buffalo, NY 14203

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

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