TITLE OF RESEARCH STUDY:

Title: Hepatitis C Treatment Psychosocial Readiness Assessment Tool (HCV-PRAT): Web Site Development

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Jeffrey Weiss, PhD
Physical Address: 17 East 102nd Street, 6th Floor West, Room 6-150, New York, NY 10029-6574
Mailing Address: 1 Gustave L Levy Place, Box 1087, NY, NY 10029
Phone: 212-824-7575

WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don’t know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care at Mount Sinai.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study which might make you change your mind about participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to pilot the Psychosocial Readiness Evaluation to Prepare for hepatitis C treatment (PREP-C) for validation and dissemination to health care professionals who treat patients with chronic hepatitis C virus (HCV) infection. The PREP-C is designed to assess patient readiness for HCV treatment.

You may qualify to take part in this research study because you are a health care professional who treats patients with chronic hepatitis C virus (infection).

Funds for conducting this research are provided by Kadmon Pharmaceuticals.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last for one year. The number of people expected to take part in this research study at this site is 100. The total number of people expected to take part in this research study is 100.
DESCRIPTION OF WHAT’S INVOLVED:

If you agree to participate in this research study, the following information describes what you would be asked to do.

• Administering the PREP-C to your patients with chronic HCV to assess their readiness for HCV treatment.
• Entering the information obtained during the PREP-C interview onto the PREP-C website database.
• Provide feedback to us on your experience using the PREP-C.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

Conducting PREP-C interviews with your patients with chronic HCV to assess their readiness for HCV treatment using the PREP-C web site.

Responding to surveys to assess your experience using the PREP-C and the web site.

Voluntary participation in the interactive discussion board to provided feedback on the PREP-C instrument, the PREP-C website, and recommendations for interventions and referrals.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

There will be no cost to you for taking part in the study other than your time related to administering the PREP-C interview and entering information onto website. You will not be compensated for their participation in this research study.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits as a health care professional, may be that the the web site will be interactive and allow you to be trained in administering the PREP-C and to register for on-line entry of client data. In addition, it may serve as an educational source for your patients.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk. We will keep sensitive information locked. We will not be collecting any identifying information about your patients so there is no way in which the data can be linked to an individual person.

OTHER POSSIBLE OPTIONS TO CONSIDER:
You may decide not to take part in this research study without any penalty. The choice is totally up to you. Declining to participate in the research will in no way affect a potential subject’s employment record or status.

**IN CASE OF INJURY DURING THIS RESEARCH STUDY:**

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

**ENDING PARTICIPATION IN THE RESEARCH STUDY:**

You may stop taking part in this research study at any time without any penalty.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff at 212-824-7475. At that point you will no longer be required to participate in any of the study activities.

*If you decide to stop being in the research study, the following may occur:*

- Your login and password for the website database will be deactivated and you will no longer have access to the information on the PREP-C website database.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

**CONTACT PERSON(S):**

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number 212-824-7575.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at Mount Sinai School of Medicine at telephone number (212) 824-8200 during standard work hours for any of the following reasons:
Study ID #: IF1369700

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

DISCLOSURE OF FINANCIAL INTERESTS:

The study is financed by Kadmon Pharmaceuticals.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

No patient information will be entered onto the database. The PREP-C website database will be de-identified with assigned study identification. Names, addresses, medical record numbers, and any other direct identifiers are not required fields for the database usage.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2522 or the New York City Commission of Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.
MOUNT SINAI SCHOOL OF MEDICINE AND HOSPITAL
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
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Form Version Date: 10-Feb-2012

Signature Block for Capable Adult
Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

DO NOT SIGN THIS FORM AFTER THIS DATE → 03/20/13

Signature of subject

Date and Time

Printed name of subject

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent

Date and Time

Printed name of person obtaining consent

If the individual cannot read, a witness is required to observe the consent process and document below:
My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date and Time

Printed name of person witnessing consent process

This Section For IRB Official Use Only
This Consent Document is approved for use by Mount Sinai’s Institutional Review Board (IRB)
Form Approval Date: 3/21/12
DO NOT SIGN AFTER THIS DATE → 3/20/13
Rev. 2/1/2011
IRB Form HRP-502a