Informed Consent for providers: Sponsor-Investigator Initiated CRI #15-05

Title: Bridging Care to HCV Treatment Among Opioid Dependent Patients on Buprenorphine/naloxone Maintenance Therapy: A Pilot Study of Treating HCV with Epclusa at a Psychiatrist-staffed Outpatient Addiction Clinic

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May 05, 2017
WIRB®

PSYCHIATRIST INFORMED CONSENT

TITLE:	Bridging Care to HCV Treatment Among Opiate Dependent Patients on Buprenorphine/naloxone Maintenance Therapy: A Pilot Study of Treating HCV with Epclusa at a Psychiatrist-staffed Outpatient Addiction Clinic
PROTOCOL NO.:	15-05 WIRB® Protocol #20170423
PROTOCOL VERSION/DATE:	V6.2 February 23, 2017
FUNDER:	Gilead
SPONSOR:	Community Research Initiative of New England
INVESTIGATOR:	Dr. Amy Colson, MD, MPH Schrafft's City Center 529 Main Street, 3rd Floor Boston, Massachusetts 02129 United States
SITE(S):	Outpatient Addiction Services Cambridge Health Alliance 26 Central Street Somerville, MA 02143 United States Tel: 617-665-1000 Email: zschuman@challiance.org
STUDY-RELATED PHONE NUMBER(S):	Amy Colson, MD, MPH 617-502-1700 617-502-1799 (24-hours)
SUB-INVESTIGATOR(S):	Zev Schuman-Olivier, MD

INTRODUCTION

You are being asked to take part in a clinical research study involving a currently available treatment for Hepatitis C virus (HCV). The treatment, Epclusa, is approved by the Food and Drug Administration for treatment of HCV. It is a fixed-dose combination (FDC) tablet which combines two separate medicines called Sofosbuvir (SOF) and Velpatasvir (VEL) into one tablet for the treatment of the Hepatitis C virus (HCV). If you participate in this study you will be a prescriber of this medication to HCV infected patients receiving buprenorphine/naloxone therapy at the Outpatient Addiction Services clinic.

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.

WHAT IS THE PURPOSE OF THIS STUDY?

The main purpose of this study is to assess the safety and effectiveness and tolerability of Epclusa in HCV treatment naïve and treatment-experienced (including treatment intolerant) subjects with chronic HCV infection who regularly attend a clinic for buprenorphine/naloxone therapy. The study also seeks to design and assess a curriculum and mentorship program to support psychiatrists with managing HCV infection.

You are being asked to be in this study because you:

- Are a psychiatrist who has agreed to train for and implement an HCV treatment protocol at Outpatient Addiction Services clinic at CHA

HOW LONG WILL THIS STUDY LAST?

The study is expected to last for 48 weeks and to enroll 20 HCV-infected individuals who receive buprenorphine/naloxone therapy at the Outpatient Addiction Services clinic at CHA.

Psychiatrists employed at that clinic will prescribe and manage the study treatment, participate in the mentorship program and complete questionnaires about their experience managing HCV disease for study participants during the study.

THE STUDY:

WHAT ARE THE PROCEDURES OF THIS STUDY?

If you agree to participate in the mentorship and survey assessments, you will be asked to review this informed consent and to sign it after all your questions have been answered. You will have access to the consent and a sub investigator or investigator to discuss your questions prior to consenting. If you agree to participate, you will sign the consent with the study team prior to any study related activities.

Prior to initiating treatment of HCV with eligible subjects, you will attend a scheduled mentorship training program conducted by Dr. Amy Colson, an infectious diseases physician who is the Principal Investigator of the study. The curriculum will review all necessary information about the management of HCV treatment. The following topics will be reviewed:

- Pathogenesis of HCV infection
- Goals of therapy/benefits of curing HCV
- Pre-treatment assessment, including diagnosis of Cirrhosis
- Usage of Epclusa

Prior to the scheduled mentorship training program, and after four months of prescribing HCV therapy to study participants, you will be asked to complete a brief survey to determine your comfort level with providing care for patients with HCV infection.

Regularly schedule weekly telephone support for psychiatrist-prescribers will be provided by Dr. Amy Colson throughout the study.

Subject's Responsibilities

As a participating psychiatrist in this study, it is your responsibility:

- to come to the initial training session
- to complete surveys as requested by the study team and outlined in the protocol
- to participate in regularly scheduled weekly support calls with the Principal Investigator

WHAT ARE THE RISKS AND DISCOMFORTS?

RISKS AND BENEFITS

Possible Risks of the Study

All responses to surveys will be kept strictly confidential. However, there is a small theoretical risk that survey confidentiality may be compromised.

Possible Benefits of the Study

There is no guarantee that you will receive personal benefit from participating in this study. One theoretical perceived benefit may be through participating in the mentorship program about HCV treatment you will broaden your knowledge about the topic. The results of this study may benefit future patients receiving HCV treatment.

WHAT ARE MY ALTERNATIVES?

Your alternative is not to participate in this study.

WILL YOU BE INFORMED OF NEW FINDINGS?

Any new information that is learned about the study conduct and changes to treatment protocols for HCV infection while the study is being conducted will be given to you. This new information might cause you to change your mind about staying in the study. You may be asked to sign a new consent form with the new information to document show that you have been told about this new information.

HOW WILL YOUR CONFIDENTIALITY BE PROTECTED?

You have a right to privacy. All information collected during this study is confidential as far as the law allows. The questionnaires you complete will identify you by a provider-subject number but NOT BY NAME. As part of their oversight responsibilities, the research records may be reviewed by the U.S. Food and Drug Administration (FDA) and Western Institutional Review Board (WIRB).

The results of the study may be presented at scientific meetings or published. *Your identity will never be used in these reports.*

WILL THERE BE ANY COSTS FOR PARTICIPATING IN THIS STUDY?

There will be no cost to you.

WILL THERE BE COMPENSATION FOR PARTICIPATION IN THIS STUDY?

You will not receive any payment or compensation for your participation in this study.

CAN YOU WITHDRAW FROM THE STUDY?

Before you can decide if you want to be in this study, it is important that you know that:

- You do not have to be in this study.
- You can decide to stop being in this study at any time.
- Your decision will not result in any penalty or loss of any benefits to which you may be entitled.

Outpatient Addiction Services clinic management does not urge, influence or encourage anyone who works at the clinic to take part in a research study. Your participation in this study is completely voluntary. You may withdraw from the study at any time and for any reason. Your decision not to participate in the study, or a decision on your part to withdraw from the study, will have no effect whatsoever on your employment status. You may refuse to participate or you may withdraw from the study at any time without penalty or prejudice.

Removal from study:

You may be removed from the study without your consent for any of the following reasons, or other administrative reasons:

- If you do not participate in the mentorship program as described
- If the study is canceled by Gilead, CRI, the FDA, or the IRB

NAMES OF CONTACTS FOR QUESTIONS ABOUT THE STUDY:

Dr. Amy Colson
Staff office: 617-502-1700
Off hours number: 617-502-1799

You should call Dr. Amy Colson or the study staff and study doctor you have been working with for the following reasons:

- If you think you may have a study-related issue
- If you have questions, concerns, or complaints about the study procedures, medication, etc.

If you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, WA 98374-2115
Office: (360) 252-2500
(800) 562-4789
Fax: (360) 252-2498
Email: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

VOLUNTEER'S STATEMENT:

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about being in this study I may contact Dr. Amy Colson, MD, MPH at Community Research Initiative of New England at 617-502-1700.

I understand that my participation in this research project is voluntary. I know that I may quit the study at any time.

If I have any questions about my rights as a research subject in this study, I may contact:

Western Institutional Review Board (WIRB)
1019 39th Avenue SE, Suite 120
Puyallup, WA 98374-2115
Office: (360) 252-2500
(800) 562-4789
Fax: (360) 252-2498
Email: help@wirb.com

I have read and understand the above information. I agree to be in this study. I have been given a copy of this signed and dated form for my records.

I understand that I do not give up any of my legal rights by signing this consent form.

Study Participant (signature)	Date	Time

Print Participant's Name

Person who explained this study (signature)	Date	Time

Print Name of Person who explained this study