

Document Coversheet

Study Title: Increasing Access to Hepatitis C Treatment in Opioid Endemic Rural Areas: The Kentucky Viral Hepatitis Treatment (KeY Treat) Study

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	11/26/2018
NCT Number:	NCT05722743
IRB Number	47239
Coversheet created:	6/25/2026

Statistical Analyses

Analyses will be conducted via a generalized linear model (GLM) framework that can incorporate flexible covariate adjustment and multiple outcome types (e.g., binary, quantitative, poisson, time-to-event) with a compatible link function. This modeling flexibility provides robust investigation into the various research questions of interest. General analyses are described below based on the distribution of the dependent (outcome) variable.

Aims 1 - 3 – Treatment Uptake, Completion and SVR. The dependent variables are all dichotomous, and therefore GLM with a binary outcome specified is proposed to examine the predictors of treatment uptake, completion and SVR.

Aim 4 – Re-infection. While the dependent variable is dichotomous, time-to-event analyses will be utilized. Given that the exact date of re-infection is unknown, the outcome will be modeled using discrete time survival analysis, whereby time is represented in two separate blocks (0-6 months post-treatment completion, 6-12 months post treatment completion).

PROTOCOL TYPE

Which IRB

☒ Medical ☐ NonMedical

Protocol Process Type

☐ Exemption
☐ Expedited (Must be risk level 1)
☒ Full

IMPORTANT NOTE: Once you have saved your choices under "Which IRB" and "Protocol Process Type", you will not be able to change your selections. If your application is deemed eligible for a different Protocol Process Type, it may be necessary to create a new application.

Please see below for guidance on which selections to make, and/or download the IRB Introduction Packet for more details [\[PDF\]](#). If you still have questions about which IRB or Protocol Process Type to choose, please contact the Office of Research Integrity (ORI) at 859-257-9428 prior to saving your selections.

Which IRB

The Medical IRB reviews research emanating from the Colleges of Dentistry; Health Sciences; Medicine; Nursing; Pharmacy and Health Sciences; and Public Health.

The Nonmedical IRBs review research originating from the Colleges of Agriculture; Arts & Sciences; Business & Economics; Communications & Information; Design; Education; Engineering; Fine Arts; Law; and Social Work. The Nonmedical IRB does not review studies that involve administration of drugs or studies that involves invasive medical procedures, regardless of from what college the application originates.

Which Protocol Process Type

Under federal regulations, an investigator's application to conduct a research project involving human subjects can be processed by the IRBs in three ways:

- by full review;
- by exemption certification [\[see categories\]](#);
- by expedited review [\[see categories\]](#);

The preliminary determination that a research project is eligible for exemption certification or expedited review is made by the investigator. For assistance in determining which review process type your IRB application is eligible for, please see the IRB Introduction Packet [\[PDF\]](#).

PROJECT INFORMATION

Title of Project: (If applicable, use the exact title listed in the grant/contract application). ⓘ

Increasing Access to Hepatitis C Treatment in Opioid
Endemic Rural Areas: The Kentucky Viral Hepatitis
Treatment (KeY Treat) Study

Short Title Description

Note: "Short Title" should consist of a couple key words to easily identify your study - these key words (rather than the whole title) will be displayed on the Dashboard in the listing for your study.



KeY Treat

Anticipated Ending Date of Research Project: 7/31/2023

Number of human subjects ⓘ

900

Study is/will be open to new subject enrollment (or data/specimen collection): ⓘ ☒ Yes ☐ No

PI CONTACT INFORMATION

The Principal Investigator's (PI) contact information is filled in automatically based on who was logged in when the application was created (with LinkBlue ID). If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be the same person listed below.

If you are not the Principal Investigator, do NOT add yourself as study personnel. You may change the PI contact information on an application that is in Researcher edit mode by:

- clicking the "Change Principal Investigator" link below;
- searching for the PI's name using the search feature;
- clicking "Select" by the name of the Principal Investigator, then "Save Contact Information".

You will automatically be added as study personnel with edit authorization so you can continue editing the application.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to [myUK](#) and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a '[Name Change Form](#)' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the [HR Benefits Office](#) for additional information.

Note: Principal Investigator (PI) role for E-IRB access

The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*). 

[Change Principal Investigator:](#)

First Name: Jennifer	Room# & Bldg: 845 Angliana Avenue
Last Name: Havens	Speed Sort#: 40508
Department: Behavioral Science - 7H150	Degree:
PI's Employee/Student ID#: 00048869	Rank:  Associate Professor
PI's Telephone #: 8593236553	Dept Code: 7H150
PI's e-mail address: Jennifer.Havens@uky.edu	PI's FAX Number: 8592575232
PI is R.N. ☐ Yes ☒ No	Trained: Yes
	Date Trained: 5/13/2016

Do you, the PI, have a [significant financial interest](#) related to your responsibilities at the University of Kentucky (that requires disclosure per the [UK administrative regulation 7:2](#))?

☐ Yes ☒ No

RISK LEVEL

Indicate which of the categories listed below accurately describes this protocol

- ☐ (Risk Level 1) Not greater than minimal risk
- ☐ (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individuals subjects
- ☐ (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ☐ (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests [\[45 CFR 46.102\(i\)\]](#)

Download UK's guidance document on assessing the research risk for additional information on risk [\[PDF\]](#) 

SUBJECT DEMOGRAPHICS

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) to

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations

(Please note: The IRB will expect this information to be reported at Continuation Review time):

Enter Numbers Only!		
Ethnic Origin	#Male	#Female
American Indian/Alaskan Native:	0	0
Asian:	0	0
Black African American:	20	15
Hispanic/Latino:	5	5
Native Hawaiian/Pacific Islander:	0	0
White/Caucasian:	450	405
Other or Unknown:	0	0

If unknown, please explain why:

Indicate the categories of subjects and controls to be included in the study. Depending on the subject category applicable to your research you may be required to complete additional forms. [Note, if the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check mark populations which the research does not specifically target. For instance, a large record review of a diverse population may incidentally include a prisoner or an international citizen, but, if the focus or intent of the study has nothing to do with that status, you do not need to check those category(ies).]

Check All That Apply (at least one item must be selected)

ADDITIONAL INFORMATION:

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☒ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal

Please visit the [IRB Survival Handbook](#) under the named topic:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults: Link to required [Form](#)

And/Or:

- UKMC Residents or House Officers [see [requirement of GME](#)]

Material

- ☒ Prisoners
- ☐ Non-English Speaking
- ☐ International Citizens
- ☒ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☐ Patients
- ☒ Appalachian Population

- Non-English Speaking [see [instructions for recruitment](#) and E-IRB Research Description section on same topic]
- International Citizens [[HTML](#)] (DoD SOP may apply [[PDF](#)])
- Military Personnel and/or DoD Civilian Employees (DoD SOP may apply [[PDF](#)])

The next questions involve assessment of the study relative to potential recruitment of subjects with impaired consent capacity (or likelihood).

- ☐ Check this box if your study does not involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). (you will not need to answer the impaired consent capacity questions)

Does this study focus on adult subjects with any of the clinical conditions listed below that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

☒ Yes ☐ No

If Yes, go to the following link and complete and attach the indicated form unless you are filing for an exemption certification: <https://ris.uky.edu/ori/oriforms/formt/Scale.asp>

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

PRISONERS

SECTION 1. (45 CFR 46.306)

For studies involving ***prisoners**, or for studies recruiting subjects at risk of becoming involuntarily confined/detained in a penal institution or other type of incarceration during the research (i.e., subjects with substance abuse history), respond to the questions in Sections 1 and 2, and any other sections that apply. For information on restrictions and regulatory requirements, see ORI's [Research Involving Prisoners web page](#).

For research involving prisoners, the definition of minimal risk refers to the probability and magnitude of **physical** or **psychological** harm that is normally encountered in the daily lives, or in the routine medical, dental or psychological examination of healthy persons.

Indicate the category that best represents your research by checking the applicable box below, and explain in the space provided for that category why your research meets the criteria.

Prisoner Categories

- ☒ **Category 1 (45 CFR 46.306(a)(2)(i)) My research involves the study of possible causes, effects, processes of incarceration, and of criminal behavior.** (Processes of incarceration can be interpreted broadly to include substance abuse research, half-way houses, counseling techniques, criminal behavior, etc ...)
- ☐ **Category 2 (45 CFR 46.306(a)(2)(ii)) My research involves the study of prisons as institutional structures, or of prisoners as incarcerated persons.** (This category is usually used fairly narrowly – i.e., looking at prisoner diet, conditions of prison, etc...)
- ☐ **Category 3 (45 CFR 46.306(a)(2)(iii)) My research involves the study of conditions particularly affecting prisoners as a class.** (This category is rarely used – i.e., vaccine trials, research on hepatitis, social and psychological problems such as alcoholism, drug addiction, sexual assaults. Minimal risk studies should not go under this category.)
- ☐ **Category 4 (45 CFR 46.306(a)(2)(iv)) My research involves the study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.** (Rare for research involving placebo or control groups to fall in this category because of the difficulty in justifying improvement of the health or well-being of the subject being given placebo or in a control group.) Note: Contact the Office of Research Integrity at (859) 257-9428 for more information.

Explain the research practices that will be used in this study and how they are intended to improve the health and well-being of the participants:

There is high potential for participants' hepatitis C to be cured if they take a once-per-day pill for 12 weeks. If participants are incarcerated during that time, we are seeking approval to bring the medication to be dispensed by the jail's medical staff. For those who become incarcerated after they have completed treatment, it is important to know whether they are continuing to engage in risk behaviors for HCV, so we can understand their risk for re-infection after cure. No participants will be recruited from prison/jail.

SECTION 2. (45 CFR 46.305)

When an IRB is reviewing a protocol in which a prisoner will be a subject, the IRB must find and document justification that six additional conditions are met. Describe in the space provided how each condition applies to your research.

Condition 1. Advantages acquired through participation in the research, when compared to the prisoners' current situation, are not so great that they impair their ability to weigh risks.

Describe the possible advantages that can be expected for prisoner participants:

Participants in this study will have been recruited prior to incarceration and will not be

recruited from the jail. We are seeking approval to merely continue their study medications while incarcerated, or to complete their follow-up interview (if they have completed the medication regimen).

Condition 2. Risks are the same as those that would be accepted by non-prisoners.

Describe the possible risks that can be expected for prisoner participants and justify that they are the same as for non-prisoners:

The side effects of the study drug do not differ, and therefore risks would be the same. There is some risk that receiving the medication in the jail would reveal their HCV status, which is why we are asking for them to consent to the drug being delivered to the jail.

Condition 3. Procedures for selection are fair to all prisoners and are immune from intervention by prison authorities in prisons; control subjects must be randomly selected.

a) Describe how prisoners will be selected for participation:

N/A

b) Describe what measures will be taken to prevent intervention by prison authorities in the selection process:

N/A

Condition 4. Parole boards cannot take into consideration a prisoner's participation in research. Informed consent must state participation will not impact parole.

Describe what measures are in place to ensure parole boards are not influenced by prisoners' participation in research and how prisoners will be told their participation (or refusal or withdrawal from) will not impact parole:

N/A

Condition 5. For studies that require follow-up, provisions are made including consideration for the length of individual sentences; informed consent must reflect provisions for follow-up.

Describe what provisions have been made for follow-up and how this information will be relayed to the prisoner participants:

If a participant is due for follow-up and it comes to our attention that they are in the local jail, we will attempt to set up the interview in jail (only if they have agreed to be followed up in jail). These follow-up procedures will be described to participants during the consent process.

Condition 6. Information about the study is presented in a language understandable to prisoners.

Describe what efforts have been made to present information about the study in a language understandable to the prisoner population:

N/A

SECTION 3. Only complete if applicable: Epidemiologic Research Involving Prisoners

Effective June 20, 2003, DHHS adopted policy that allows waiver of the requirement for documenting applicability of a [\(45 CFR 306\(a\)\(2\)\)](#) category (as found in Section 1 of this form) for certain epidemiologic research involving prisoners. This waiver applies to epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-subjects.

☐ Check this box if your research meets all three criteria listed below, then provide justification in the space provided.

1. I request a waiver for meeting the category conditions under Section 1 of this form.
2. My research involves epidemiologic research intended to describe the prevalence/incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease; **and**
3. Prisoners are not the sole focus of my research.

Justify how the research presents no more than minimal risk and no more than inconvenience to the subjects:

SECTION 4. Only complete if applicable: Prisoners are not the targeted population

Although prisoners may not be the target population for your research, a subject could become a prisoner during the course of the study (particularly if studying a subject population at high-risk of incarceration).

Note: If you did not receive IRB approval for involvement of prisoners, and a subject becomes a prisoner during the study, **all research interactions and interventions** with, and obtaining identifiable private information about, the now-incarcerated participant **must cease** until IRB approval has been issued for their continuation in the research. If you need IRB approval for a prisoner subject to continue participation in your research, select and complete the applicable category from Section 1, complete section 2 and this section, then submit for IRB review.

In special circumstances in which the Principal Investigator asserts that it is in the best interest of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research prior to satisfying the requirements of Subpart C. However, subsequent IRB review and approval of this completed form, documenting that the requirements of Subpart C are met, is required.

☑ Prisoners are not a target population for my research, but a subject became a prisoner during the study and I am seeking IRB approval so the subject can continue participation in the research.

Explain the importance of continuing to intervene, interact, or collect identifiable private information during the participant's incarceration:

There is high potential for participants' hepatitis C to be cured if they take a once-per-day pill for 12 weeks. If participants are incarcerated during that time, we are seeking approval to bring the medication to be dispensed by the jail's medical staff. For those who become incarcerated after they have completed treatment, it is important to know whether they are continuing to engage in risk behaviors for HCV, so we can understand their risk for re-infection after cure.

SECTION 5. Kentucky (KY) Department of Corrections (DoC) Approval

Review the following conditions and determine whether any apply to your study:

- active recruitment of participants from a correctional facility (prison, jail, or community corrections institution);
- active recruitment of individuals under community supervision from a state probation and parole office.

If any of the above conditions apply to your research, go to the website for the [Kentucky Department of Corrections Policy and Procedures, Management Information and Research \(Chapter 5\)](#) for information about [submitting a proposal for DoC approval of research \[PDF\]](#) including the DoC approved Research Consent and Research Agreement (5.1.G.1).

If your research involves a certificate of confidentiality or the Department of Corrections is directly involved in the study as a sponsor (or otherwise), contact David Kinsella, Legal Counsel, at David.Kinsella@uky.edu, or 859-323-1161, for additional information.

INFORMED CONSENT/ASSENT PROCESS/WAIVER

For your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and revise to be in accord with your research project.

Additional Resources:

- Sample Repository/Registry/Bank Consent ([PDF](#)) ([Word](#))
- [Instructions for Proposed Informed Consent Document](#)
- [Instructions for Proposed Assent Form](#)

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; **DELETE OUTDATED FILES** -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.

Document Types that do NOT get an IRB approval stamp are:

- "Highlighted Changes",
- "Phone Script", and
- "Sponsor's Sample Consent Form".

You must check the box for at least one of the consent items and/or check mark one of the waivers, then if applicable attach the corresponding document(s) as a PDF (if open to enrollment).

After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!



Check All That Apply

- ☐ Informed Consent Form (and/or Parental Permission Form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script (and/or Assent Script)
- ☒ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol

Attachments

Attach Type	File Name
Informed Consent/HIPAA Combined Form	KeYTreatConsent.FINAL.pdf

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for the informed consent process, or alteration of some or all of the elements of informed consent (i.e. medical record review, deception research, or collection of biological specimens), complete Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

- ☐ I am requesting waiver of the requirement for the informed consent process.

☐ I am requesting alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered, and/or omitted, and justify the alteration.

SECTION 2.

The IRB may consider your request provided that **all** of the following conditions apply to your research and are appropriately justified. Explain in the space provided for each condition how it applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

If you are requesting IRB approval for waiver of the requirement for documentation of informed consent (i.e. telephone survey or mailed survey, internet research, or certain international research), your research activities must fit into one of two regulatory options:

- 1) The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves participants who use illegal drugs).
- 2) The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script).

Select the option below that best fits your study, and explain in the space provided how your study meets the criteria for the selected regulatory option.

Note: The IRB cannot waive the requirement for documentation or alter the consent form for FDA-regulated research unless it meets Option #2 below. FDA does not accept Option #1.

Note: Even if a waiver of the requirement for documentation is approved by the IRB, participants must still be provided oral or written (e.g., cover letter) information including all required and appropriate elements of consent so they have the knowledge and opportunity to consider whether or not to participate. To help ensure required elements are included in your consent document, please use the **Cover Letter Template** as a guide: *English-* [\[WORD\]](#), *Spanish-* [\[WORD\]](#) The cover letter template was developed specifically for survey/questionnaire research; however, it may be useful as a guide for developing a consent document for other types of research as well.

Option 1

- a) The only record linking the participant and the research would be the consent document:

- b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant must be asked whether (s)he wants to sign a consent form; if the participant agrees to sign a consent form, only an IRB approved version should be used.

Option 2

- a) The research presents no more than minimal risk to the participant:

- b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

STUDY PERSONNEL

Do you have study personnel who will be assisting with the research?

After selecting 'Yes' or 'No' you must save by hitting the 'Save Study Personnel Information' button. 

 Yes  No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is being completed to meet the requirements of a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed as such below.
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR, MR) or 'Other Review', and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature, search for applicable personnel first, then click "select" by the listing for the person you want to add as study personnel to your protocol. For each individual selected, be sure to specify responsibility in the project, whether authorized by the principal investigator to obtain informed consent, AND denote who should regularly receive E-IRB notifications.

NOTE: Study personnel are required to receive human research protection (HSP) training before implementing any research procedures (e.g., CITI). For information about mandatory training requirements for study personnel, visit UK's [FAQ's on Mandatory Training web page](#), or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (Jen.Hill@uky.edu) for credit.

Study personnel assisting in research project: 

Add Personnel

My Study Personnel	Last Name	First Name	Responsibility In Project	Role	A C	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	Removed?	Last Updated	Recorded Training	SFI
Details	Fardo	David	Co-Investigator	SP	N	N		P	Y	05/24/2017	N	10/02/2018	10084887	N
Details	Fraser	Hannah	Data Analysis/Processing	SP	N	N		N	Y	03/03/3000	Y	11/09/2018	N809	N
Details	Hoven	Ardis	Co-Investigator	SP	N	N		P	Y	10/17/2018	N	10/02/2018	00052314	N
Details	Jent	Susan	Data Collection	SP	Y	N		P	Y	08/07/2017	N	10/02/2018	10013137	N
Details	Lofwall	Michelle	Co-Investigator	SP	N	N		P	Y	11/10/2017	N	10/02/2018	00061851	N
Details	Rosenau	Jens	Medical Supervisor	SP	N	N	MD	P	Y	01/12/2018	N	10/02/2018	10715125	N
Details	Staton	Christa	Co-Investigator	SP	N	N		P	Y	10/24/2018	N	10/02/2018	00008256	N
Details	Vickerman	Peter	Co-Investigator	SP	N	N		N	Y	03/03/3000	Y	11/09/2018	N808	N
Details	Walsh	Sharon	Co-Investigator	SP	N	N		P	Y	05/12/2017	N	10/02/2018	00058631	N
Details	Weiss	Jeffrey	Co-Investigator	SP	N	N		N	Y	03/03/3000	Y	11/09/2018	N581	N
Details	Young	April	Co-Investigator	SP	N	N		P	Y	04/24/2017	N	10/02/2018	10157385	N

RESEARCH DESCRIPTION

****!!!!PLEASE READ!!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.

Workaround(s):

- Save your work often to avoid losing data.
- Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

The overarching goal of the Kentucky Viral Hepatitis Treatment Project (KeY Treat) is to increase hepatitis C virus (HCV) treatment access and delivery in a rural Appalachian community, which is in the midst of the opioid/hepatitis C virus (HCV) syndemic. KeY Treat is a clinical research study seeking to determine whether removing barriers (cost, insurance, specialist, abstinence) associated with accessing direct-acting antivirals (DAAs) for the treatment of HCV will impact health in Perry County, Kentucky. HCV is a serious chronic liver disease that can have fatal consequences, including cirrhosis, end-stage liver disease, and hepatocellular carcinoma (HCC). Kentucky is among the leaders in acute HCV infections, largely attributed to prescription opioid injecting in rural areas that has been aptly dubbed the opioid/HCV syndemic. In our cohort of 503 rural opioid users recruited in 2008, 80% have a history of injection, the majority of whom continue to inject prescription opioids, despite reports of the transition to heroin in most of the country. To date, 347 of the 503 participants in this cohort have tested anti-HCV positive (69.8% seroprevalence overall), 115 of which represent incident cases, primarily among young PWID (22.5 cases per 100 person years in PWID <25 years). Of those, approximately 70% are RNA-positive, and are, therefore, eligible for HCV treatment with direct acting antivirals (DAAs). However, our data suggest low uptake of HCV treatment, lack of partner notification of HCV status, and social networks that facilitate continued transmission of the virus. This is further facilitated by low treatment uptake rates even among motivated participants who meet Medicaid/insurance requirements for HCV treatment in Kentucky and elsewhere in the U.S. There is a clear need for increasing access to HCV treatment to not only prevent additional infections, but also to lower the risk of advanced liver disease and HCC in a region that is already plagued by marked health disparities. To that end, KeY Treat is both timely and significant. HCV pharmacotherapies now offer revolutionary advancement over previous ribavirin/pegylated interferon- α -based treatment, with its clinical utility limited by low efficacy, numerous contraindications, high toxicity, lengthy treatment duration and subsequent non-adherence. Direct-acting antivirals (DAA) agents, have reported greater than 90% of patients consistently achieving sustained virologic response (SVR)/cured. Moreover, significantly decreased toxicity has been observed, along with considerably shortened treatment duration. Equally important, interferon-free regimens allow for all-oral drug administration, removing the barrier of regular interferon injections and associated impacts on morbidity and patient compliance. The high rates of SVR as well as ease of treatment for the newer HCV regimens may serve not only to cure the individual patient, but also to allow a scale-up of treatment for preventing further transmission among HCV-positive people who inject drugs (PWID); a treatment as prevention approach. However, as efficacious as these treatments are as both a tool to cure the disease and prevent further transmission, treatment initiation rates with DAAs are low among PWID. Barriers to treating PWID are many; concerns about re-infection, cost, prior authorization requirements for insurance, and fibrosis stage, are often cited by providers as rationale for not treating this vulnerable population. This lack of access is unfortunate given that modeling data suggest DAAs are tremendously promising as a mechanism to eliminate HCV among PWID. An ongoing study of HCV treatment awareness being conducted by the PI suggests that rural PWID are indeed aware of DAAs (83.9%), and of those, all but one (n=56) indicated they would be willing to take DAAs if it were available to them. Most participants are also aware of the high out-of-pocket costs for treatment, which is upwards of \$90,000 for an 8- to 12-week regimen. However, SNAP participants indicate that the uptake of DAAs would be high if the drug is administered locally (94.6%) and is provided at low or no cost (94.6%). These findings speak to the awareness of DAAs as a tool for treating HCV in those at highest risk and demonstrate feasibility, as many participants indicated a willingness to engage in treatment. A recent MMWR report suggests that high HCV rates observed in our cohort are NOT unique to Appalachian Kentucky.⁸ In fact, similar rates have been reported in rural Tennessee, Virginia and West Virginia, indicating the results from this study will be highly generalizable to other settings, which further speaks to the potential impact of KeY Treat. There is little doubt that the HCV epidemic can be addressed, even in regions with health disparities or rapidly increasing epidemics. Further, treating HCV, even among active PWID, is more cost effective than waiting till they stop injecting, which is one of the many reasons why KeY Treat is critically important. However, many of the analyses focused on treating HCV in PWID populations also note the importance of providing additional harm reduction services, and specifically medication assisted treatment (MAT) and syringe services programs (SSPs) to achieve optimal treatment outcomes. Indeed, a recent model of rural Scott County, Indiana (site of a 2015 HIV outbreak among PWID) demonstrated that the scale-up of MAT and SSP is crucial for optimizing and sustaining the impact of HCV treatment on HCV prevalence and incidence. This is because of their direct impact on reducing the primary and re-infection incidence of HCV. This comprehensive approach to achieving SVR and preventing re-infection is a vital aspect of KeY Treat, and if shown to be efficacious and cost-effective, has great potential to move the field forward by demonstrating how to increase access to HCV treatment in rural, underserved populations. The study investigators have secured a drug donation from Gilead Sciences, Inc. for sofosbuvir/velpatasvir (Epclusa®), a 12-week, once per day, pan-genotypic DAA tablet with a favorable side effect profile. Participants who are re-infected or are nonresponsive to Epclusa®

will be offered Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), which will also be made available to KeY Treat participants at no cost. Both DAA combinations will be used per AASLD/IDSA HCV guidelines. To facilitate portability of KeY Treat to other rural settings, a mid-level provider model will be utilized, whereby HCV treatment services will be provided locally by nurse practitioners who have access to a hepatology team at the University of Kentucky via a telehealth model (Extension for Community Health Outcomes [ECHO]). KeY Treat will be co-located with the local Syringe Services Program (SSP), and subsidized Medication Assisted Treatment (MAT) services will be offered to those with opioid use disorder. All Perry County residents age 18 and over who are HCV RNA-positive will be eligible for treatment in KeY Treat with no out-of-pocket costs, including people who use drugs (PWUD) or inject drugs (PWID).

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section.

1) To determine HCV treatment uptake among rural residents who are chronically infected with hepatitis C. The outcome is the proportion of participants who enroll in the study that initiate treatment with Epclusa®. It is hypothesized that PWUD will be as likely to initiate treatment as non-PWUD. 2) To examine completion of the 12-week treatment course among rural residents. This outcome is the proportion of participants returning for their 12-week blood draw having had all medication dispensed. It is hypothesized that treatment completers are more likely to have stable housing compared to non-completers. 3) To determine the proportion of participants achieving sustained virologic response (SVR). This outcome (SVR-12) is defined as having undetectable RNA levels at the 12-week post-treatment-completion blood draw. It is hypothesized that participants who did not reply to daily text reminders for medication adherence will be less likely to achieve SVR compared to those who did reply to daily reminders. 4) To examine re-infection rates among rural drug users achieving SVR. Re-infection is defined as having detectable RNA after having achieved SVR and will be measured at 6- and 12-months post-SVR. It is hypothesized that PWID not utilizing the SSP will be more likely to be re-infected at follow-up. 5) Examine changes in incidence and prevalence of HCV in Perry County compared to Pike County. It is hypothesized that there will be significant reductions in both incidence and prevalence as a result of the HCV treatment study in Perry compared to Pike County over the five-year period. 6) Use mathematical modeling to guide and evaluate the impact and cost-effectiveness of the KeY Treat intervention. It is hypothesized that KeY Treat will be a cost-effective strategy for decreasing HCV prevalence and incidence.

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting [community-based participatory research \(CBPR\)](#), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a research repository describe the repository design and operating procedures. For relevant information to include, see question 22 of the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [\[PDF\]](#).

KeY Treat is a non-randomized controlled trial comparing incidence and prevalence of hepatitis C in Perry and Pike Counties. In the intervention county (Perry), hepatitis C RNA positive residents (N=900) will be offered treatment with sofosbuvir/velpatasvir, a once-per-day, all oral, direct acting antiviral with a favorable side effect profile. In the intervention county, additional individual-level outcomes will be examined, including treatment entry, completion, SVR (cure) and re-infection.

Attachments

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Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners or others who are likely to be vulnerable. If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of these groups requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- The proposed dates of enrollment (beginning and end);
- The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button.

Potential participants age 18 years and older testing HCV Ab-positive will provide a blood sample to establish baseline RNA levels, and RNA-positive participants are considered eligible for KeY Treat. Potential participants testing Ab- or RNA-negative will be invited to re-screen every six months throughout the enrollment period. Perry County residency (verified via ID card showing local address, lease, utility bill, etc.) will be required because there is a limited supply of drug. Women who are pregnant will be ineligible for treatment with the study drug during their pregnancy, but will be asked to return after their delivery for further evaluation and possible enrollment in the KeY Treat Project. Enrollment will commence in early 2019, and participants will continue to be recruited, treated, and/or followed through 2023. There are no restrictions based on gender (other than pregnancy) or race/ethnicity; however, given the racial/ethnic make-up of Perry County is largely Caucasian, we anticipate the majority of participants will be Caucasian.

Attachments

Subject Recruitment Methods & Privacy: Describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information. Describe the setting in which an individual will be interacting with an investigator. If applicable, describe proposed outreach programs for recruiting women and minorities as participants in clinical research.

Please note: Based upon both legal and ethical concerns, the UK Medical Institutional Review Board (IRB) will not approve finder's fees for research studies.

Given the broad eligibility criteria, whereby both people who use drugs (PWUD) and non-PWUD will be recruited, we propose multiple recruitment mechanisms. In our ongoing studies with PWUD in Perry County, peer-referral (respondent driven sampling [RDS]) has proven to be an effective recruitment tool. We will also recruit PWUD who have agreed to be contacted from within our existing IRB-approved studies, syringe services program (SSP), BHG (medication assisted treatment [MAT] provider who is conducting HCV screening with no referral mechanisms), and flyers posted in areas we have previously identified as having a high concentration of PWUD. For non-PWUD participants, we will be relying on referrals from primary care/local health providers, ER-based screening (Focus program), and the health department to recruit participants. If non-PWUD participants express interest in recruiting peers, they will be invited to do so, but it will not be a requirement for participation for PWUD or non-PWUD. Prior to implementing KeY Treat, we will utilize local media to publicize the project in print and on television, and advertise for study participants via radio and print ads. There is also the issue of those who are unaware of their HCV status. As part of the local campaign to raise awareness of the study, we will conduct free HCV screenings in the study office and the Perry County Health Department. Finally, KeY Treat will set up a booth for confidential screenings at Black Gold, an annual event in September that is heavily attended by Perry County community members.

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Advertising: Specify if any advertising will be performed. If yes, please see "[IRB Application Instructions - Advertisements](#)" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment" on ORI's [IRB Survival Handbook](#) web page for the *PI Guide to Identification and Recruitment of Human Subjects for Research* [D7.0000] document [\[PDF\]](#). If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities. [i](#)

Advertisements are TBD. We will secure IRB approval for any proposed advertisements prior to posting.

Attachments

Informed Consent Process: Describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent (Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application), steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent (i.e., research involving adult subjects with impaired consent capacity) and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page. For additional information, see the [Informed Consent Standard Operating Procedures \(SOPs\)](#) (PDF).

Informed Consent for Research Involving Emancipated Individuals

If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the [Informed Consent SOP](#) (PDF).

Informed Consent for Research Involving Non-English Speaking Subjects

If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see [IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture](#).

Research Repositories

If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the "[University of Kentucky Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use](#)" (PDF).

Given that KeY Treat eligibility is determined via laboratory results, participants will be consented prior to commencing any study-related activities. Two copies of the consent form will be in each interview packet – one for the participant to review and keep and one for the interviewer to obtain signatures and store in a locked cabinet at the researcher's office at the Center on Drug and Alcohol Research. As explicitly stated in the consent form, participation is completely voluntary and there are no penalties or prejudice of any kind for not participating in the study. The informed consent will be read aloud by an interviewer, stressing the voluntary nature of the study and the ability to withdraw from the study at any point. The participant will have the opportunity to ask questions and refuse if he/she desires. If the participant agrees to participate in the study, he/she will sign the informed consent included in this application. The consent will only be in English; however, in our experience conducting research in the target community, we have not had any participants who were non-English speakers. The consent will only be given at the baseline visit.

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Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

The following clinical protocol was developed under the guidance of the study hepatologist, Dr. Jens Rosenau, in accordance with AASLD/IDSA guidelines. The protocol will continue to be refined in response to local conditions and resources until implementation, and any proposed changes to said protocol will be sent for IRB approval prior to implementation. The protocol is intended to follow best practices/standard of care for the treatment of HCV, with additional allowances for the investigators to apply rigorous scientific practices for the research aspects of the study. While the treatment of HCV with DAAs is fairly straightforward, less is known about treating active drug users and other RNA-positive individuals in rural areas; therefore, we are proposing nine TOTAL visits, including two pre-treatment visits, four treatment-related visits, and three visits to determine re-infection (6- and 12-months post-SVR). Because thorough determination of medication adherence and long-term re-infection rates are not part of standard clinical practice, there will be three additional visits, totaling nine, as indicated above. The primary drug that will be used for treatment is sofosbuvir/velpatasvir (Eplclusa®), a 12-week, once per day, pan-genotypic DAA with a favorable side effect profile. Doses of Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) will also be available to the clinicians, in cases where participants are non-responsive or are re-infected. A crucial component of KeY Treat is the delivery of comprehensive services to facilitate navigation of the HCV treatment cascade. Community-based providers will be contracted to deliver MAT and SSP to all participants locally. Medication Assisted Treatment (MAT). All participants enrolled in the KeY Treat Project who meet DSM-V criteria (established at Visit 1) for an opioid use disorder (OUD) will be offered MAT. It is hypothesized that participants with opioid use disorder who engage in MAT will be more likely to initiate treatment, complete treatment, and achieve SVR compared to those who do not utilize treatment. Infrastructure for providing MAT has improved in Perry County in the past year. The KeY Treat investigators will contract with Behavioral Health Group (BHG), a Perry County licensed opioid treatment program, to offer three evidence-based therapies: buprenorphine (both oral and injectable [once FDA approved]), methadone and naltrexone. SSP. The SSP in Perry County currently operates three days per week in three-hour time blocks, which will be adjusted for greater demand. Care Coordination Care coordination services will also be offered to all participants by a trained social worker. Potential areas of intervention will be identified by the PREP-C (see Data Collection instruments), which will be administered by the care coordinator. Examples of potential services that care coordinators may

deliver include HCV treatment education, motivational interviewing, referrals to substance use and mental health services, assistance with insurance and entitlements, transportation, legal services, crisis services, child care, and employment. Visit Schedule The clinical and research components of the study will be kept separate to minimize bias on the part of the clinicians, researchers, and participants alike. Consistent with clinical research practices, clinical staff will not have access to research survey responses; likewise, research staff will not have access to laboratory or other clinical findings. The timing and activities for the study are as follows, and key outcomes are bolded under the Research heading (please see attached table for the visit schedule). Adherence Every effort will be made to assure KeY Treat participants are taking the study drug as prescribed. First, daily text reminders will be sent to participants, and if they respond to the text, they will get a small monetary reward at the next visit. This will encourage those who get new cell phones during the treatment period to inform study staff of the new phone number so they can continue to receive the text reminders. The timing of the reminder (and thus ingestion of the medication) will be decided between the participant and their clinician based on other medications they are taking and convenience of the participant. The study drug does not have a food requirement, and there are very few contraindications, so it can be taken any time of day. The wording of the text will be generic to protect their confidentiality as a research subject. A KeY Treat team member will send a sample text while the participant is in the office, and a response will be attempted to establish this line of communication. Participants without a cell phone can choose another form of reminder. However, based on information from previous studies in Perry County, we anticipate that the majority of participants will have access to a text-enabled smartphone through a local program that provides these devices to low-income residents. Electronic blister packs will also be utilized to increase adherence. These blister packs monitor whether the box has been opened and if not opened by a certain time each day, will send a text reminder to the participant to take the medication. Adherence will also be assessed early in the active treatment phase of KeY Treat. Participants will be asked to return at 2-weeks post-treatment initiation for a blood draw. As noted in the treatment literature, if the participant is taking the medication as prescribed, there should be almost immediate declines in RNA levels. If declines are not observed from baseline to the 2-week treatment follow-up, the case manager will intervene to determine if there are barriers to medication adherence that can be addressed to get them back on track. Adherence may be affected if participants are jailed while in the active medication phase. If the participant consents to being followed-up in jail, the following procedures will be employed for jail-based medication dispensing: 1. DAILY VINE CHECKS. a. A list of all participants in the active treatment phase will be updated daily by the Study Director. This list will have the participant number and the medication start date. Using this list, a Research Assistant will check Vine (<https://kcoj.kycourts.net/CourtNet/Search/Index>) to determine if any participants in the active treatment phase have been incarcerated in the past 24-hours (or 48-hours for weekends). b. If active treatment phase participant(s) are found to be incarcerated in KRRJ, the lead study nurse will be notified. The nurse will call up to KRRJ to arrange a drop off time. c. Using the medication start date, the lead nurse will determine the amount of medication that needs to be brought to KRRJ. The lead nurse will fill out the Medication Dispensing Form with the participant number, date, and amount of medication that is being dispensed. They will also check the box indicating that the drug is being brought to KRRJ and that the drug is being dispensed. They will also enter their initials as the person dispensing the drug to KRRJ. Once they arrive at the jail, they will hand the drug to the clinician on duty and request that they sign the Medication Dispensing Form indicating that they received the drug. d. If a participant is released prior to completion of the 12-week medication regimen, the lead nurse will go back to the jail to retrieve the remaining medication. A new entry will be made in the Medication Dispensing Form with the participant number and date, as well as the amount of medication that is being returned. The box will be checked to indicate return of medication. The jail clinician and lead nurse will sign off when the take-back is complete. Treatment Failure/Re-Infection It is anticipated that a subset of participants will be non-adherent with the treatment medication or will need to be discontinued from treatment due to lack of efficacy or adverse events. AASLD/IDSA guidelines will be followed for discontinuation of treatment. Patient treatment failures will be discussed individually during regular meetings between the study hepatologist/ECHO team and the nurse practitioners, and an appropriate course of action will be determined. Medication re-initiation will be considered on a case-by-case basis and Vosevi® may be used in place of Epclusa®. It is also anticipated that there will be KeY Treat participants who are re-infected after achieving SVR. They will be offered an additional course of treatment with a new medication, and referred to the case manager to address any potential issues that may have contributed to re-infection. Gilead Sciences, Inc. has agreed to provide Vosevi® to those who are re-infected or non-responsive to Epclusa®.

Attachments

Attach Type	File Name
ResearchProcedures	VisitScheduleAttachment.docx

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

Clinical Data 1. HCV antibody test. OraQuick® HCV Rapid Antibody Test (OraSure, Bethlehem, PA). Conducted at baseline. 2. HIV antibody test. OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Test (OraSure, Bethlehem, PA). Conducted at baseline and final visits (for those testing HIV-negative). 3. HCV quantitative RNA. Measured at baseline, after two weeks of treatment (to assess compliance), at end of treatment, 12-weeks post-treatment completion, 6- and 12-months post-treatment completion (to assess re-infection). Blood will be sent to laboratory with the study ID ONLY and, when results are returned, they will be entered in a database by participant number and reported to participants at their next visit. 4. HCV genotype. Although the study medication is pan-genotypic, genotype may be an important predictor of treatment failure. One-time blood test at first visit. 5. Fibrosis score (measured from 0-5). We will use common laboratory measures to assess for fibrosis. Participants will be eligible for treatment with any fibrosis score; however, the extent of liver damage may be an important predictor of treatment outcomes. Fibrosis score is also important to rule out

cirrhosis; KeY Treat participants with cirrhosis will be treated, but referred to the UK Center for Excellence in Rural Health for long-term surveillance for hepatocellular carcinoma. 6. DSM-V OUD. The case manager will conduct a clinical interview at Visit 1 to determine whether the participant meets DSM-V criteria for an opioid use disorder, and if so, they will be offered MAT services. 7. Dispensed medication. A database will be developed and maintained for entering when medication is dispensed to the participant. This will be conducted at set intervals (see Visit Schedule, above). 8. Medication adherence. In addition to the measurement of adherence using RNA results, we will also ask about self-reported adherence. This will be asked by both the research staff and clinical staff, in separate interviews, so that if the participant is not comfortable sharing with their clinician that they are non-adherent, the research interviewer may still be able to gather this vital information. Responses to text reminders will be maintained in a database, and the proportion of "answered" texts will be calculated and correlated to treatment response. 9. MAT utilization. MAT utilization will be assessed, and a record linkage will be made between the MAT provider and KeY Treat for those participants who enrolled in MAT through a referral to BHG from the study. 10. Side effects. Self-reported side effects will be assessed at each study visit post-treatment initiation and entered into the participants' clinical record as well as a side-effect database that can be used for analytic purposes. 11. Medication history. A detailed medication history will be collected during the initial visit, and every visit where medication is being dispensed to assess for potential drug-drug interactions. The PREP-C is attached for review, as is a draft of the Baseline Questionnaire. Follow-up questionnaires will be sent for review prior to participant administration.

Attachments

Attach Type	File Name
DataCollection	PREPC Evaluation.pdf
DataCollection	BaselineKeYTreat.pdf

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see [FDA Guidance](#)). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see [IRB Application Instructions - Off-Site Research](#) web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

The research will be conducted within Perry County, KY in a building leased specifically by UK for KeY Treat and will therefore be a UK site (site TBD - address will be submitted to IRB once identified). Sites being considered are all within 2 miles of the emergency room, BHG and Ky River Health Department (see below). It is anticipated that this site will house four to six clinicians and four to six research staff members. Participants will be consented and the treatment protocol administered at this location. Additional resources include the syringe services program at the Kentucky River Health Department and Behavioral Health Group (BHG), both of whom we will be contracting with to provide additional services (syringe services and treatment for opioid use disorder [OUD]). Research will not be conducted at these sites, however; participants will be referred if they seek treatment or a source of sterile syringes. The study site will be outfitted with exam rooms, small laboratory for conducting blood draws and processing samples, office space and a reception area. There will also be a drug safe to store the donated drug. Staff will be provided with laptop and desktop computers to collect and enter data and telehealth equipment to conduct regular consultations with the Lexington-based medical team, Drs. Lofwall and Rosenau. Password-protected wifi will be installed for staff so that they data may be uploaded to UK's secure servers on a regular basis. Public wifi will also be available for participants. Participants will also be provided with a list of local resources such as housing, child care, and mental health treatment. These will be given to the participant with their consent form, if requested, or at the discretion of study staff.

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

During the screening process, it is possible that volunteers may feel uncomfortable answering personal questions about their health, psychiatric and drug use histories. However, they may stop answering questions at any point (and are informed of this option during the informed consent process). During the screening, HCV antibody-positive subjects will also have a venipuncture in order to draw blood for testing purposes. It is possible that this could lead to bruising, infection, or a blood clot, but this risk is minimal and limited by the sterile procedures, universal precautions and well-trained nursing and phlebotomy staff. The primary risks to the study participants are related to the ingestion of the study drug. Epclusa® (sofosbuvir/velpatasvir) is a pan-genotypic direct-acting antiviral (DAA) that is taken orally, once per day, for 12-weeks. Specifically, Epclusa® is a fixed-dose combination of sofosbuvir, a HCV nucleotide analog NS5B polymerase inhibitor and velpatasvir is a HCV NS5A inhibitor. The drug is indicated for those age 18+ with chronic HCV genotypes 1-6. The two most common adverse reactions (>10% of patients) are fatigue and headache. Vosevi®

(sofosbuvir/velpatasvir/voxilaprevir) has two of the same active ingredients as Epclusa®, with the addition of voxilaprevir, a HCV NS3/4A protease inhibitor. It is also taken once per day for 12 weeks. In addition to headache and fatigue, side effects (>10%) also include diarrhea and nausea. In addition, renal function will also have to be taken into account when administering Vosevi®. Administration of this drug will be considered on a case-by-case basis for nonresponders and those who are re-infected. Given the favorable side effect profile of the primary drug, Epclusa, it is anticipated that few, if any adverse events (AEs) will occur over the course of the trial related to the study medication.

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Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

All volunteer PHI is confidential and will be protected according to the guidelines established by the Health Information Portability and Accountability Act (HIPAA). An "Authorization to use and disclose PHI for research purposes" approved by the UK IRB will be obtained. This allows the investigators on this project to use or share health information with the United States Department of Health and Human Services (DHHS) representatives, the UK IRB, the UK Office of Research Integrity (ORI), UK medical center representatives, other research collaborators or when required by law. Files will not contain the name of the participant. Instead, each participant will be assigned a unique identifying number. All written documents, including PHI, will be stored in locked cabinets at the KeY Treat Research Facility in Hazard, Kentucky. Key access will be limited to immediate clinical/research personnel. Electronic information will reside on a password-protected server maintained by the Center on Drug and Alcohol Research at the University of Kentucky. Electronic transmission via e-mail or FAX with volunteer PHI will have a statement of confidentiality. During the conduct of this project, we will maintain an active concern for providing proper protection of the welfare and rights of the research volunteers. If a volunteer chooses to receive text message reminders to aid with medication adherence, there are several protections in place to mitigate potential risks. The message will be generic in nature. KeY Treat staff will send a sample text while the participant is in the office so they know what the messaging will entail. It will not indicate that the volunteer is in the study, not mention medications or HCV. The text will come from a computerized service, so if someone other than the participant calls the number, they will not be able to determine research participation. If participants let the study staff know that their phone has been lost or stolen, texts will be discontinued. Finally, a Certificate of Confidentiality will be displayed in all KeY Treat offices. It is anticipated that there will be few side effects related to the study drug; however, to minimize the potential for adverse events, the clinical staff will thoroughly address potential side effects, request reports of potential side effects at follow-up, and will discuss potential side effects with the study hepatologist, Dr. Rosenau. In addition, participants will have access to the clinical staff to address any safety/adverse event concerns they may have. Participants who appear to be intoxicated will be asked to return when they are no longer under the influence and will be rescheduled by the clinical coordinator.

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc...), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for [Protection of Vulnerable Subjects \[C3.0100\]](#) (PDF).

The major potential benefit to participants in KeY Treat is that they will achieve sustained virologic response (SVR); e.g., cured of HCV. In addition, the potential and probable benefits to be derived by society, in general and by rural residents appear to be considerable. The major benefits of these studies are scientific and clinical ones related to the knowledge gained concerning the relative risk/benefit ratio with of treating hepatitis C in rural communities and demonstrating the benefits of removing restrictions from receiving HCV treatments. There will also be a minimal financial benefit, as participants will be compensated for completing the research questionnaires over the course of the study. Overall, the risk/benefit ratio appears favorable and the conduct of this research seems well justified.

Available Alternative Treatment(s): Describe alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

There are no alternatives, apart from not participating.

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Research Materials, Records and Privacy: Identify the sources of research material obtained from individually identifiable living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):

If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB ["Frequently Asked Questions \(FAQs\) on the Return of Research Results or Incidental Research Findings"](#) (PDF).

All self-report data to be collected by a research interviewer are solely for the purpose of this research project and will be reported in aggregate only. HIV, HCV, HBV, HAV and CBC/CMP will be obtained from blood tests administered by the KeY Treat clinicians and phlebotomist. Interview data will be collected at the study site via computer assisted personal interviewing (CAPI) software. Data collection will be carried out by project interviewers and clinical staff. Locator forms will be managed on site in Hazard in a locked file cabinet behind a locked office door. Consent and payment forms will be brought to the Center on Drug and Alcohol Research bi-weekly by research staff. These forms will be transported in fire-safe locked boxes. Security of the electronic data will be stored on a UK server with password protection with research data separated from subject identifiers. Blood samples taken among those who test HIV and/or HCV-positive may be sent to an independent laboratory for further testing. Samples will be labeled with participant ID numbers only, never names or any identifying information.

Confidentiality: Specify where the data/specimens will be stored and how the researcher will protect both the data and/or specimens with respect to privacy and confidentiality. Address physical security measures (e.g., locked facility, limited access); data security (e.g., password-protection, data encryption); safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality); and procedures employed when sharing material or data, (e.g., honest broker (if applicable), written agreement with recipient not to re-identify). If you plan to procure, store, and/or share material (tissue/specimens/data) expressly for use in current or future research, describe measures that you will take to secure and safeguard confidentiality and privacy.

Provide a time table for destroying the data/specimens and identify how they will be destroyed, or provide rationale for perpetual maintenance [Note: The investigator is responsible for retaining the signed consent and assent documents and IRB research records for at least six years after study closure as outlined in the [Study Closure SOP](#) (PDF). If the research falls under the authority of FDA or other regulatory agency, the investigator is responsible for retaining the signed documents and IRB records for the period specified if longer than six years after completion of the study]. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data/specimens with entities not affiliated with UK.

NIH-funded genomic research: The National Institutes of Health (NIH) [Genomic Data Sharing \(GDS\) Policy](#) sets forth expectations that ensure the broad and responsible sharing of genomic research data consistent with the informed consent of study participants from which the data was obtained. If you are submitting genomic data to an NIH data repository, describe your NIH data sharing plan.

Please note: The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "[Confidentiality and Data Security Guidelines for Electronic Data](#)" (PDF).

Also please note that storage of data on cloud services may not be appropriate and is subject to applicable university policies regarding the use of cloud services. If deemed too sensitive or inappropriate to be stored or collected using cloud services, the IRB may require an alternate method of data storage in accordance with applicable university policies and the electronic data security guidance document referenced above.

If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriate protected.

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Every effort will be made in the protection of human participants and issues relating to participant confidentiality. A Certificate of Confidentiality is now provided for all NIH studies, and will be displayed in all public spaces, as well as each office where participant assessments will take place. Participants will also receive a copy of both the Certificate, and the consent form. All information for this study is electronic, except for the consent, locator and payment information. Those three pieces of information contain participant names, and therefore will be stored in locked file cabinets at the Hazard location until they are transported for permanent storage at Dr. Havens' office in Lexington. Once enrolled in the study, participants will be assigned a unique number that will be used for all correspondence between research staff. Electronic information will be entered using this number, and the list linking the names and numbers will be kept in a double password protected database on the PI's computer. Electronic transmission via e-mail or FAX with volunteer PHI will have a statement of confidentiality. During the conduct of this project, we will maintain an active concern for providing proper protection of the welfare and rights of the research volunteers. If a volunteer chooses to receive text message reminders to aid with medication adherence, there are several protections in place to mitigate potential risks. The message will be generic in nature. KeY Treat staff will send a sample text while the participant is in the office so they know what the messaging will entail. It will not indicate that the volunteer is in the study, not mention medications or HCV. The text will come from a computerized service, so if someone other than the participant calls the number, they will not be able to determine research participation. If participants let the study staff know that their phone has been lost or stolen, texts will be discontinued. Finally, participant's identifying information will NOT be shared with Gilead Sciences, Inc.

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Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

Participants will be incentivized for completing the research-related questionnaires, peer referral and Questionnaires: 1. Baseline ((\$50) and six additional follow-up questionnaires (\$25 each) = \$200 total over the study period. 2. Peer referral (\$10 for each eligible participant) = \$60 total over the study period. 3. Text message responding (\$1 per day if respond to daily medication reminder) = \$84 over 12-weeks of active medication. In sum, participants may be remunerated a total of \$344 for completing all research-related activities.

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

There are no costs to subjects.

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, clinical research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, clinical research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data and Safety Monitoring Plan (DSMP). [Click here for additional guidance on developing a Data and Safety Monitoring Plan.](#)

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, clinical research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, [click here for additional guidance](#) for information to include with your IRB application.

If relying on an independent agent or committee for DSMB services, it is the PI's responsibility to establish the services with the agent or committee. Please be reminded that the PI must submit DSMB reports to the IRB via modification or continuing review. ⓘ

DSMP included as an attachment.

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Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

Participants will be encouraged to call the Principal Investigator with any questions or concerns that arise during the study. Phone numbers for the PI and ORI are included on the consent form that the participant will receive a copy of. It is anticipated that by providing this information, the participant will have a safe, confidential, and reliable channel to voice their concerns or questions.

Does your research involve **Non-English Speaking Subjects or Subjects from a Foreign Culture**?

☐ Yes ☒ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.

Include contact information for someone who can act as a cultural consultant for your study. The person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted. The consultant should not have any direct involvement with the study. If you do not know someone who would be willing to act as your cultural consultant, the Office of Research Integrity will try to find someone to fill this role (this may delay the approval process for your protocol). Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study. For more details, see the IRB Application Instructions on [Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture](#).

For recruitment of Non-English speaking subjects, the consent document needs to be in the subject's native language. Download the informed consent template available in the E-IRB "Informed Consent/Assent Process" section and use it as a guide for developing the consent document. (Note: Your translated consent document can be attached to your application in the "Informed Consent" section; **be sure to save your responses in this section first.**)

If research is to be conducted at an international location, identify local regulations, laws, or ethics review requirements for human subject protection. If the project has been or will be reviewed by a local Ethics Committee, attach a copy of the

review to the UK IRB using the attachment button below. You may also consult the current edition of the [International Compilation of Human Research Standards](#)

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc....)?**

☒ Yes ☐ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "[Reporting Requirements for Diseases and Conditions in Kentucky](#)" (PDF).

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online [IRB Survival Handbook](#) to download a copy of the Medical IRB's requirements for [Protection of Human Subjects in Research Involving HIV Testing \[D65.0000\]](#) (PDF), and visit the [Office for Human Research Protections web site](#) for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

HIV, hepatitis B and acute hepatitis C are reportable to the State of Kentucky, if testing is conducted in a medical office or laboratory. Although KeY Treat is research and does not fall within the reporting standards, the consent form will note that if positive, results will be reported to the State Department of Public Health.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

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- 1) involves testing a Nonsignificant Risk (NSR) Device, or
- 2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

☐ Yes ☒ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the PI assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor [IND regulatory requirements for drug trials](#) (PDF), [IDE regulatory requirements for SR device trials](#) (PDF), and [abbreviated regulatory requirements for NSR device trials](#). For detailed descriptions see [FDA Responsibilities for Device Study Sponsors](#) or [FDA Responsibilities for IND Drug Study Sponsor-Investigators](#).

- Describe your (the PI's) experience/knowledge/training (if any) in serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if you have transferred any sponsor obligations to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see [Sponsor-Investigator FAQs](#)). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the PI completed the mandatory PI-sponsor training prior to this submission?

☒ Yes ☐ No

If you (the PI) have completed equivalent sponsor-investigator training, you may submit documentation of the content for the IRB's consideration.

[Attachments](#)

HIPAA

Is HIPAA applicable? ☐ Yes ☒ No

(Visit ORI's [Health Insurance Portability and Accountability Act \(HIPAA\) web page](#) to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s): 

☐ HIPAA De-identification Certification Form

☐ HIPAA Waiver of Authorization

Attachments

Attach Type	File Name
CombinedInformedConsent	KeYTreatConsent.11.9.18.Clean.pdf
HighlightedChanges	KeYTreatConsent.11.9.18.Tracked.pdf

STUDY DRUG INFORMATION

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- [complementary and alternative medicine products](#) such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of [e-cigarettes](#) examining a potential therapeutic purpose.

Does this protocol involve testing (collecting safety or efficacy data) of a drug including an FDA approved drug, unapproved use of an FDA approved drug and/or an investigational drug?

☒ Yes ☐ No

If yes, complete the questions below. Additional [study drug guidance](#).

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

sofosbuvir/velpatasvir (Epclusa)
sofosbuvir/velpatasvir/voxilaprevir (Vosevi)

Note: Inpatient studies are required by Hospital Policy to utilize the Investigational Drug Service (IDS). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Clinic in Hazard, KY (site TBD)

Is the study being conducted under a valid Investigational New Drug (IND) application?

☐ Yes ☒ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐

Held By:

Investigator: ☐

Held By:

Other: ☐

Held By:

☐ Checkmark this if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND).

- [FDA's Expanded Access Program Information \(e.g., treatment IND\)](#)
- Guidance and definitions: "[Expanded Access SOP](#)" (PDF).

Please also complete and attach the [Study Drug Form \(PDF\)](#) (required):



Attachments

Attach Type	File Name
StudyDrug	Study Drug Attachment.KeYTreat.pdf
StudyDrug	epclusa_pi.pdf
StudyDrug	vosevi_pi.pdf

STUDY DEVICE INFORMATION

A DEVICE may be a:

- component, part, accessory;
- assay, reagent;
- software or computer/phone application;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's [Use of Any Device Being Tested in Research web page](#).

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

☐ Yes ☐ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer "no" above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE) or Humanitarian Device Exemption (HDE) application? See UK [HUD SOP](#) (PDF) for guidance.

☐ Yes ☐ No

If Yes, list IDE or HDE #(s) and complete the following:

IDE/HDE Submitted/Held by:

Sponsor: ☐

Held By:

Investigator: ☐

Held By:

Other: ☐

Held By:

☐ Check if this is a Treatment or Compassionate Use IDE under the Food and Drug Administration (FDA) Early Expanded Access program.

- [FDA's Early Expanded Access Program Information](#)
- Guidance and definitions: "[Medical Device Clinical Investigations, Compassionate Use, and Treatment IDE SOP](#)" (PDF)

Does the intended use of any device used in this study meet the regulatory [definition](#) of Significant Risk (SR) device?

☐ Yes. Device(s) as used in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential

for serious risk to the health, safety, or welfare of a subject.

☒ No. All devices, as used in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Please also complete and attach the [Study Device Form \(PDF\)](#) (required):



Attachments

RESEARCH SITES

In order for this section to be considered complete, you must click "SAVE" after ensuring all responses are accurate.

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☐ UK Classroom(s)/Lab(s)
- ☐ UK Clinics in Lexington
- ☒ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☐ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's [IRB Application Instructions - Off-site Research](#) web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

List all other non-UK owned/operated locations where the research will be conducted:*

*A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the [IRB Application Instructions - Off-Site Research](#) web page for more information.

Attachments

Attach Type	File Name
-Letter of Support & Local Context	KRRJLetterofSupport.pdf

B) Is this a multi-site study for which you are the lead investigator or UK is the lead site? ☐ Yes ☒ No

If **YES**, you must describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites in the E-IRB "Research Description" section under *Resources*.

If the non-UK sites or non-UK personnel are *engaged* in the research, there are additional federal and university requirements which need to be completed for their participation, such as the establishment of a cooperative IRB review agreement with the non-UK site. Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

RESEARCH ATTRIBUTES

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

- ☐ Academic Degree/Required Research
- ☐ Aging Research
- ☐ Alcohol Abuse Research
- ☐ Cancer Research
- ☒ Certificate of Confidentiality
- ☐ CCTS-Center for Clinical & Translational Science
- ☐ Clinical Research
- ☒ Clinical Trial
- ☐ Clinical Trial Multicenter(excluding NIH Cooperative Groups)
- ☐ Clinical Trial NIH cooperative groups (i.e., SWOG, RTOG)
- ☐ Clinical Trial Placebo Controlled Trial
- ☒ Clinical Trial UK Only
- ☒ Collection of Biological Specimens
- ☒ Collection of Biological Specimens for Banking
- ☐ Community-Based Participatory Research
- ☐ Data & Safety Monitoring Board
- ☒ Data & Safety Monitoring Plan
- ☐ Deception
- ☒ Drug/Substance Abuse Research
- ☐ Educational/Student Records (e.g., GPA, test scores)
- ☐ Emergency Use (Single Patient)
- ☐ Genetic Research
- ☐ Gene Transfer
- ☐ GWAS (Genome-Wide Association Study) or NIH-funded study generating large scale genomic data
- ☐ International Research
- ☐ Internet Research
- ☐ Planned Emergency Research Involving Waiver of Informed Consent
- ☐ Pluripotent Stem Cell Research
- ☐ Recombinant DNA
- ☒ Survey Research
- ☐ Transplants
- ☐ Use of radioactive material, ionizing radiation, or x-rays [Radiation Safety Committee review required]
- ☐ Vaccine Trials

Click applicable listing(s) for additional requirements and/or information:

- [Cancer Research \(MCC PRMC\)](#)
- [Certificate of Confidentiality](#) (look up "Confidentiality/Privacy...")
- [CCTS \(Center for Clinical and Translational Science\)](#)
- [Clinical Research](#) (look up "What is the definition of....")
- [Clinical Trial](#) (look up "What is the definition of....")

Determine if research meets [NIH definition of clinical trial](#);

*Reminder: Ensure compliance with [clinicaltrials.gov](#) registration requirements for applicable clinical trials and [Good Clinical Practice \(GCP\) training](#) requirements.

- [Collection of Biological Specimens for Banking](#) (look up "Specimen/Tissue Collection...")
- [Collection of Biological Specimens](#) (look up "Specimen/Tissue Collection...")
- [Community-Based Participatory Research](#) (look up "Community-Engaged...")
- [Data & Safety Monitoring Board](#)
- [Data & Safety Monitoring Plan](#)
- [Deception*](#)

*For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- [Emergency Use \(Single Patient\) \[attach Emergency Use Checklist\]](#) (PDF)
- [Genetic Research](#) (look up "Specimen/Tissue Collection...")
- [Gene Transfer](#)
- [HIV/AIDS Research](#) (look up "Reportable Diseases/Conditions")
- [Screening for Reportable Diseases \[E2.0000\]](#) (PDF)
- [International Research](#) (look up "International & Non-English Speaking")
- [Planned Emergency Research Involving Waiver of Informed Consent*](#)

*For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- [Use of radioactive material, ionizing radiation or x-rays for research](#)

FUNDING/SUPPORT

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply. ⓘ

☐ Not applicable

Check All That Apply

- ☐ Grant application pending
- ☒ (HHS) Dept. of Health & Human Services
- ☒ (NIH) National Institutes of Health
- ☐ (CDC) Centers for Disease Control & Prevention
- ☐ (HRSA) Health Resources and Services Administration
- ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Other:

Click applicable listing(s) for additional requirements and/or information:

- [\(HHS\) Dept. of Health & Human Services](#)
- [\(NIH\) National Institutes of Health](#)
- [\(CDC\) Centers for Disease Control & Prevention](#)
- [\(HRSA\) Health Resources & Services Administration](#)
- [\(SAMHSA\) Substance Abuse & Mental Health Services Administration](#)
- Industry (Other than Pharmaceutical Companies) [[IRB Fee Info](#)]
- [National Science Foundation](#)
- [\(DoEd\) U.S. Department of Education](#)
- [\(DoJ\) Department of Justice or Bureau of Prisons](#)
- [\(DoE\) Department of Energy Summary](#) and [Department of Energy Identifiable Information Compliance Checklist](#)
- [\(EPA\) Environmental Protection Agency](#)

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

National Cancer Institute and National Institute on Drug Abuse

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application:

Add Related Grants

Grant/Contract Attachments

Attach Type	File Name
GrantContract	aimsandresplan.FINAL.pdf

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP [\[PDF\]](#) and DoD Summary [\[PDF\]](#) for details)

☐ Yes ☒ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

[DOD SOP Attachments](#)

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

OTHER REVIEW COMMITTEES

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? *[If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.]*

☐ Yes ☒ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC)--Attach [required IBC materials](#)
- Radiation Safety Committee (RSC)-- For applicability, see [instructions](#) and/or upload form [\[WORD\]](#) [\[PDF\]](#)
- Radioactive Drug Research Committee (RDRC)--[information](#)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)**--Attach MCC PRMC materials, if any, per [instructions](#)
- See requirement of [Office of Medical Education \(OME\)](#)
- See requirement of [Graduate Medical Education Committee \(GME\)](#)

Attachments

**** If you are proposing a study involving cancer research, be sure to have "Cancer Research" marked in the E-IRB "Research Attributes" section.** If your study involves cancer research, ORI will provide a copy of your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The [MCC PRMC](#) is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

Do you want specific information inserted into your approval letter? ☐ Yes ☒ No

Approval Letter Details (e.g., serial #):

Submission Description: If you wish to have specific details included in your approval letter (e.g., serial #, internal tracking identifier, etc...), type in the box below exactly what you wish to see on the approval letter. What you type will automatically appear at the top of all approval letters, identical to how you typed it, until it is changed by you (Hint: don't include instructions or questions to ORI staff as those will appear in your approval letter). **If these details need to be changed as a result of revisions, continuation review, or modifications to the application, you are responsible for updating the content of the field below accordingly.**

Protocol/Product Attachments - For each item checked, please attach the corresponding material.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Drug Documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.)
- ☐ Device Documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.)
- ☐ Other Documents

Protocol/Product Attachments

Attach Type	File Name
AddInfoProtocol	Community Resource Guide.docx

NOTE: [Instructions for Dept. of Health & Human Services \(DHHS\)-approved protocol](#)

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

Additional Materials:

If you have other materials you would like to include in your application for the IRB's consideration, please attach using the Attachments button below.

[To view what materials are currently attached to your application, go to "Application Links" in the menu bar on the left and click "All Attachments".]

Attachments

Attach Type	File Name
AdditionInfoConsiderations	47239 Havens2.pdf
AdditionInfoConsiderations	Screeener.Updated.docx
AdditionInfoConsiderations	Response.11.8.18.docx
AdditionInfoConsiderations	47239 Havens.pdf
AdditionInfoConsiderations	Havens 47239 comments from IRB.pdf

SIGNATURES (ASSURANCES)

On all IRB applications there is a requirement for additional assurances by a Department Chairperson (or equivalent) [hereafter referred to as "Department Authorization"], and when applicable, a Faculty Advisor (or equivalent), which signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans.

For a list of responsibilities reflected by signing the Assurance Statement, download the guidance document "[What does the Department Chairperson's Assurance Statement on the IRB application mean?](#)" 

Required Signatures:



First Name	Last Name	Role	Department	Date Signed	
Carl	Leukefeld	Department Authorization	Behavioral Science	10/09/2018 05:05 PM	View/Sign
Jennifer	Havens	Principal Investigator	Behavioral Science	10/08/2018 01:47 PM	View/Sign

Department Authorization

☒ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator is knowledgeable of the additional regulatory requirements of the sponsor and can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☒ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Please notify the personnel required for signing your IRB application after sending for signatures. Once all signatures have been recorded, you will need to return to this section to submit your application to ORI.

SUBMISSION INFORMATION

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed; otherwise your submission for IRB review and approval will not be able to be sent to the Office of Research Integrity/IRB.

Please remember to update, when applicable, the Approval Letter Details text box under the Additional Information section to ensure verbiage you want on your approval letter is accurate.

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and a message will be forthcoming to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Modification Request Information

Select One:

- ☐ This modification does not increase risk to study participants.
☐ This modification may or will increase risk to study participants.

Is this modification request due to an Unanticipated Problem/Adverse Event, or Protocol Violation?

- ☐ Yes ☐ No

In your professional opinion, does this modification involve information that might relate to a subject's willingness to continue to take part in the research?

- ☐ Yes ☐ No

If yes, state how the information will be communicated to subjects (i.e., re-consent, send letter, etc.):

For each proposed modification, include a justification.

Example: Jane Doe, MD, is being added as co-investigator because she has expertise with the subjects on this protocol. She has completed human subject protections training, and is authorized to obtain consent.

The prisoner risk category was changed from 3 to 1, since there is minimal risk to participants who are jailed during follow-up.

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
🔗	Stamped Consent Form	KeYTreatConsent.11.9.18.Clean.pdf		0.127	braisor	11/26/2018 11:13:23 AM
🔗	Stamped Consent Form	KeYTreatConsent.FINAL.pdf		0.164	braisor	11/26/2018 11:13:23 AM
🔗	ApprovalLetter	ApprovalLetter.pdf		0.059	braisor	11/26/2018 11:13:23 AM
🔗	AdditionInfoConsiderations	Screener.Updated.docx	Screener Updated	0.137	jhave2	11/16/2018 12:22:31 PM
🔗	AdditionInfoConsiderations	47239 Havens2.pdf	IRB Requested Revision Ltr.	0.014	braisor	11/16/2018 11:33:24 AM
🔗	AddInfoProtocol	Community Resource Guide.docx	Community Resource List for Dr. Haven's study	0.053	braisor	11/13/2018 3:05:45 PM
🔗	AdditionInfoConsiderations	Havens 47239 comments from IRB.pdf	Additional Information & Request for Clarification	0.086	braisor	11/13/2018 10:41:27 AM
🔗	HighlightedChanges	KeYTreatConsent.11.9.18.Tracked.pdf	Consent form (Tracked Changes)	0.097	braisor	11/12/2018 1:05:58 PM
🔗	CombinedInformedConsent	KeYTreatConsent.11.9.18.Clean.pdf	Consent form (Clean)	0.089	braisor	11/12/2018 1:04:02 PM
🔗	AdditionInfoConsiderations	Response.11.8.18.docx	ResponseLetter	0.135	jhave2	11/9/2018 4:11:56 PM
🔗	-Letter of Support & Local Context	KRRJLetterofSupport.pdf	Letter of Support from Jail	0.050	jhave2	11/9/2018 4:07:33 PM
🔗	AdditionInfoConsiderations	47239 Havens.pdf	IRB Requested Revision Ltr.	0.031	braisor	10/30/2018 3:04:04 PM
🔗	GrantContract	aimsandresplan.FINAL.pdf	NIH Grant Submission	0.405	jhave2	10/15/2018 5:13:26 PM
🔗	Informed ConsentHIPAA Combined Form	KeYTreatConsent.FINAL.pdf	KeYTreatConsent	0.158	jhave2	10/9/2018 9:09:17 AM
🔗	DataCollection	BaselineKeYTreat.pdf	BaselineQuestionnaire	0.288	jhave2	10/8/2018 1:44:00 PM
🔗	DataCollection	PREPC Evaluation.pdf	HCVReadinessQuestionnaire	0.048	jhave2	10/8/2018 12:43:56 PM
🔗	ResearchProcedures	VisitScheduleAttachment.docx	Visit Schedule	0.094	jhave2	10/6/2018 9:15:35 AM
🔗	StudyDrug	vosevi_pi.pdf	VoseviInsert	0.342	jhave2	10/5/2018 4:29:27 PM
🔗	StudyDrug	epclusa_pi.pdf	EpclusaInsert	0.291	jhave2	10/5/2018 4:29:06 PM
🔗	StudyDrug	Study Drug Attachment.KeYTreat.pdf	Study Drug Form	0.314	jhave2	10/5/2018 4:28:51 PM

Protocol Changes

Protocol Number: 47239

Prisoners PrisonerCategory changed by jhave2 on 11/19/2018 3:17:44 PM

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Prisoners PrisonerCatJustify changed by jhave2 on 11/19/2018 3:17:44 PM

Participants have the opportunity There is high potential for participants' hepatitis C to be cured if their hepatitis C disease if they take part y take a once-per-day pill for 12 weeks. If participants are incarcerated during the study. We are giving participants the option to continue their treatment in jail if they are to become incarcerated during the active treatment phase (12 weeks total). We are not recruiting participants from the at time, we are seeking approval to bring the medication to be dispensed by the jail's medical staff. For those who become incarcerated after they have completed treatment, it is important to know whether they are continuing to engage in risk behaviors for HCV, so we can understand their risk for re-infection after cure. No participants will be recruited from prison/jail.

Study Personnel Changes:

No Changes

There are no recorded changes to study personnel.

Project Information Comment by Beverly Raisor - ORI to IRB/PI on 11/19/2018 4:00:35 PM

The PI was asked to submit the 11/19/18 MR to update the prisoner category so that it is consistent with the IRB / prisoner rep. determination.