

New York State
Department of Health
AIDS Institute
Division of HIV and Hepatitis Health Care
Bureau of Hepatitis Health Care and
Health Research, Inc.

Request for Applications (RFA)
RFA# 20-0001

*Eliminating Hepatitis C by Improving Access to Hepatitis C Care and Treatment – Central
New York and Long Island Regions*

Applicants may submit no more than one (1) application in response to this RFA.

KEY DATES

RFA Release Date:	January 19, 2021
Questions Due:	February 10, 2021 by 4:00 PM ET
Questions, Answers and Updates Posted: (on or about)	February 24, 2021
Applications Due:	April 13, 2021 by 4:00 PM ET

DOH Contact Name & Address:

Colleen Flanigan, RN, MS
Director
Bureau of Hepatitis Health Care
NYS Department of Health/AIDS Institute
hepatabc@health.ny.gov

How to File an Application:

Applicants **must** submit one PDF version of the entire application (including Application Cover page, Application checklist, narrative and all attachments) to AIGPU@health.ny.gov by 4:00pm on April 13, 2021. The subject of the email line should reference *Eliminating Hepatitis C by Improving Access to Hepatitis C Care and Treatment – Central New York and Long Island Regions*. Late applications will not be accepted.

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I. INTRODUCTION

The New York State Department of Health AIDS Institute (NYSDOH AI) Division of HIV and Hepatitis Health Care, Bureau of Hepatitis Health Care, and Health Research, Inc. (HRI) announce the availability of \$900,000 annually in federal funding to increase the number of people who are treated and cured for hepatitis C (HCV) in the Central New York and Long Island regions of New York State. As part of New York State's (NYS's) plan to eliminate HCV, this will be accomplished by creating a primary care-based integrated multidisciplinary model of care to serve all populations in an equitable manner, especially those currently underserved and socially disadvantaged. Funded applicants will conduct targeted outreach, linkage and care coordination to assist people with HCV, and HIV/HCV in accessing timely HCV medical care and appropriate supportive services in a primary care setting.

A. Background/Intent

On March 16, 2018, Governor Andrew M. Cuomo announced his commitment to eliminate HCV as a public health problem in NYS. To achieve this goal, concerted efforts are needed to ensure access to timely diagnosis, care and treatment for all people with HCV. An estimated 2.4 million people are living with HCV in the United States.¹ In NYS, an estimated 116,000 people have chronic HCV.² One in five persons living with HIV is coinfecting with HCV. Injection drug use, associated with the ongoing opioid epidemic, is the driving force perpetuating the HCV epidemic in NYS. Most new HCV cases occur among people who inject drugs (PWID), especially in non-urban areas where access to HCV prevention, care, and treatment services is limited.

Fortunately, new treatment regimens have revolutionized HCV care, allowing for most patients to be treated with all-oral, well-tolerated, short duration direct acting antiviral therapy. Treatment can be delivered effectively by non-specialists in a range of clinical settings with cure expected in more than 95% of people receiving HCV treatment.^{3,4,5} Current clinical guidelines support HCV treatment for most patients, including people with co-occurring conditions such as active substance use, mental health, or HIV.^{6,7} Scaling up access to HCV treatment is essential to

¹Hofmeister MG, Rosenthal EM, Barker LK, Rosenberg ES, Barranco MA, Hall EW, Edlin BR, Mermin J, Ward J, Ryerson AB. Estimating Prevalence of Hepatitis C Virus Infection in the United States, 2013-2016. *Hepatology* 2019;69 (3):1020-1031.

²Rosenberg ES, Rosenthal EM, Hall EW, Hofmeister MG, Sullivan PS, Dietz P, Mermin J, Ryerson AB. Prevalence of Hepatitis C Virus Infection in US States and the District of Columbia, 2013 to 2016. *JAMA Netw Open*. 2018 Dec; 1(8): e186371.

³Asselah T, Marcellin P, Schinazi RF. Treatment of hepatitis C virus infection with direct-acting antiviral agents: 100% cure? *Liver Int*. 2018;38 Suppl 1:7-13.

⁴Kapadia SN, Marks KM. Hepatitis C Management Simplification From Test to Cure: A Framework for Primary Care. *Clinical Therapeutics*. 2018, 40(8): 1234-1245.

⁵Kattakuzhy S, Gross C, Emmanuel B, Teferi G, Jenkins V, Silk R, RN, MPH, Akoth E, Thomas A, Ahmed C, Espinosa M, Price A, Rosenthal E, Tang T, Wilson E, Bentzen S, Masur H, Kotttilil S. Expansion of Treatment for Hepatitis C Virus Infection by Task Shifting to Community-Based Nonspecialist Providers *Ann Intern Med*. 2017 Sep 5; 167(5): 311-318.

⁶American Association for the Study of Liver Diseases, Infectious Diseases Society of America. HCV guidance: Recommendations for testing, managing, and treating hepatitis C. 2018. Available at: <http://www.hcvguidelines.org/>. Accessed March 26, 2019.

⁷New York State Department of Health. Treatment of Chronic HCV Infection with Direct-Acting Antivirals. Available at: <https://www.hivguidelines.org/hcv-infection/>. Accessed March 26, 2019.

NYS's elimination efforts, as curing HCV improves individual health by preventing liver disease complications and improves population health by preventing further HCV transmission.^{4,5,8, 9}

However, to benefit from these therapeutic advances, people with HCV must first be identified, engaged and linked to HCV care and treatment services. It is estimated only half of people with HCV are aware of their status.¹⁰ Even when their status is known, many people diagnosed with HCV are still not linked to appropriate HCV care and treatment for variety of reasons. Barriers to prevention and care services are often related to social and structural inequities, such as poverty, homelessness, behavioral health, and criminalization of substance use that is further exacerbated by stigmatization.^{11,12} In order to treat patients' health concerns, there is increasing recognition of the need to address the underlying social determinants of health that shape a person's overall well-being.¹³

Populations with the highest prevalence of undetected and untreated chronic hepatitis also tend to be among the most medically underserved and challenging to reach.^{14,15} Provision of off-site HCV screening and education, patient navigation and collaboration with other organizations serving the community have demonstrated success in reaching and identifying people with HCV who are often marginalized by the health care system.^{10,15,16,17} Linkage and care coordination interventions improve patient outcomes, particularly for hard-to-engage and hard-to-treat populations, by proactively assessing and addressing the social and structural barriers that prevent people from engaging and remaining in care and prevention.¹⁸

Integration of on-site HCV care and treatment in primary care settings further improves the HCV care continuum substantially, as demonstrated by the success of the NYSDOH AI-funded HCV Care and Treatment initiative, in which 85% of patients initiating therapy completed treatment. Primary care providers are well positioned to build trusting supportive relationships with patients

⁸Hellard M, Doyle JS, Sacks-Davis R, Thompson AJ, McBryde E. Eradication of hepatitis C infection: the importance of targeting people who inject drugs. *Hepatology*. 2014;59(2):366-369.

⁹Tada T, Kumada T, Toyoda H, et al. Viral eradication reduces all-cause mortality, including non-liver-related disease, in patients with progressive hepatitis C virus-related fibrosis. *J Gastroenterol Hepatol*. 2017;32:687-694.

¹⁰Ford MM, Jordan AE, Johnson N, Rude E, Laraque F, Varma JK, Hagan H. Check Hep C: A Community-Based Approach to Hepatitis C Diagnosis and Linkage to Care in High-Risk Populations. *J Public Health Manag Pract*. 2018 Jan/Feb;24(1):41-48.

¹¹Milne R, Price M, Wallace B, Drost A, Haigh-Gidora I, Nexil FA, Fraser C. From Principles to practice: Description of a novel equity-based HCV primary care treatment model for PWID. *International Journal of Drug Policy* 26 (2015) 1020-1027.

¹²Midgard H, Weir A, Palmateer N, et al. HCV epidemiology in high-risk groups and the risk of reinfection." *Journal of Hepatology*. 2016;65:S33-S45.

¹³Katz A, Chateau D, Enns JE, Valdivia J, Taylor C, Walld R, McCulloch S. Association of the Social Determinants of Health With Quality of Primary Care. *Ann Fam Med*. 2018;16:217-224.

¹⁴Ramirez G, Cabral R, Patterson M, et al. Early Identification and Linkage to Care for People with Chronic HBV and HCV Infection: The HepTLC Initiative. *Public Health Rep*. 2016;131 Suppl 2:5-11.

¹⁵Ford MM, Johnson N, Desai P, Rude E, Laraque F. From Care to Cure: Demonstrating a Model of Clinical Patient Navigation for Hepatitis C Care and Treatment in High-Need Patients. *Clin Infect Dis*. 2017 Mar 1;64(5):685-691.

¹⁶Norton BL, Voils CI, Timberlake SH, Hecker EJ, Goswami ND, Huffman KM, Landgraf A, Naggie S, Stout JE. Community-based HCV screening: knowledge and attitudes in a high-risk urban population. *BMC Infect Dis*. 2014, 14:74

¹⁷Trooskin SB1, Poceta J, Towey CM, Yolken A, Rose JS, Luqman NL, Preston TW, Chan PA, Beckwith C, Feller SC, Lee H, Nunn AS. Results from a Geographically Focused, Community-Based HCV Screening, Linkage-to-Care and Patient Navigation Program. *J Gen Intern Med*. 2015 Jul;30(7):950-7.

¹⁸Deming R, Ford MM, Moore, MS, Perumalswami P, Weiss J, Wyatt B, Shukla S, Litwin A, Reynoso S, Larague F. Evaluation of a hepatitis C clinical care coordination programme's effect on treatment initiation and cure: A surveillance-based propensity score matching approach. *J Viral Hepat*. 2018 Nov;25(11):1236-1243.

who may be reluctant to seek care and encourage HCV treatment initiation.¹⁹ Integration of HCV treatment into multidisciplinary primary care settings limits structural barriers associated with specialty care and maximizes access to treatment; improves coordination of comprehensive care; and reduces missed opportunities to address the multiple health care needs of patients.^{4,20,21,22}

To impact the HCV epidemic and move towards elimination, models of care are needed to optimize the HCV care continuum by: outreaching to people who are most at risk and identifying those with HCV; proactively addressing the social and structural barriers that prevent them from engaging in care and prevention; facilitating health systems navigation and patient support; and creating convenient, accessible, multidisciplinary methods of HCV care and treatment delivery.²³

The intent of this RFA is to increase access to HCV care and treatment in Central New York and Long Island regions by creating a primary care-based integrated model of care to serve all populations in an equitable manner, especially those currently underserved and socially disadvantaged. The goals of this RFA are to:

- Increase the number of people living with HCV who are linked to care;
- Increase HCV treatment initiation and completion rates; and
- Increase the number of people cured of HCV.

This will be accomplished by conducting targeted client outreach and recruitment and by providing care coordination, peer-delivered services, and HCV care and treatment utilizing a multidisciplinary care team approach in a primary care setting.

B. Available Funding

Up to \$900,000 in federal funding is available annually to support up to 3 awards.

Funding will be allocated as stated in the chart below. Annual awards will not exceed \$300,000.

Regions	Annual Award Amount	Maximum Number of Awards
Central New York: Cayuga, Herkimer, Jefferson, Lewis, Madison, Oneida, Onondaga, Oswego, and St. Lawrence	\$300,000	0-1
Long Island: Nassau and Suffolk	\$300,000	0-2

¹⁹ Bass SB, Jessop A, Maurer L, et al. Mapping the barriers and facilitators of HCV treatment initiation in methadone maintenance therapy patients: implications for intervention development. J Health Commun. 2018;23(1):177-127.

²⁰ Vema M, Navvaro V. Patient-Centered Care: A new Paradigm for Chronic Liver Disease. Hepatology 2015; 62(4):988-990.

²¹ Zuckerman A1, Carver A1, Chastain CA2. Building a Hepatitis C Clinical Program: Strategies to Optimize Outcomes. Curr Treat Options Infect Dis. 2018;10(4):431-446. doi: 10.1007/s40506-018-0177-5. Epub 2018 Oct 18.

²² Coyle C, Moorman AC, Bartholomew T, Klein G, Kwakwa H, Mehta SH, Holtzman D. The HCV care continuum: linkage to HCV care and treatment among patients at an urban health network, Philadelphia, PA. Hepatology. 2019 Jan 11. doi: 10.1002/hep.30501

²³ Andermann A. Taking action on the social determinants of health in clinical practice: a framework for health professionals. CMA. 2016; 188(17-18):E473-E483

Applicants are requested to select their primary region of service on the cover page of the application. The primary region of service for the application should be based on the location where the largest number of clients is served. This does not preclude an applicant from proposing to serve one or more counties outside of the selected primary region of service in the same application. If an applicant fails to indicate a primary service region, it will be assigned a primary service region based on the location where the largest number of clients is proposed to be served.

Applicants may submit no more than one (1) application in response to this RFA. If more than one (1) application is submitted in response to this RFA, the first application that is received will be reviewed and considered for funding. All other applications will be rejected.

- Awards will be made to the highest scoring applicants in each region, up to the maximum number of awards indicated for that region.
- If there is an insufficient number of acceptable applications (scoring 70 or above) received from any region, HRI/the NYSDOH AI reserves the right to
 - Fund an application scoring in the range of 60-69 from a region and/or
 - Apply unawarded funding to the next highest scoring applicant(s) in the other region until the maximum number of awards per region is met.
- If there is an insufficient number of fundable applications, the maximum number of awards may not be met. HRI/NYSDOH AI reserves the right to re-solicit these services if there is an insufficient number of fundable applications.
- If funding remains available after the maximum number of acceptable scoring applications is awarded to each region, HRI/NYSDOH AI reserves the right to exceed the maximum number of awards. Remaining funding will be awarded to the next highest acceptable scoring applicant(s) from any region until the remaining funding is exhausted or awards have been made to all acceptable scoring applicants.
- HRI/NYSDOH AI reserves the right to revise the award amounts as necessary due to changes in availability of funding.

Should additional funding become available, HRI/NYSDOH AI may select an organization from the pool of applicants deemed approved but not funded. If it is determined that the needed expertise/services are not available among these organizations, HRI/NYSDOH AI reserves the right to establish additional competitive solicitations.

II. WHO MAY APPLY

A. Minimum Eligibility Requirements

All applicants must meet the following minimum eligibility requirements:

- Applicant must be a not-for-profit health care organization licensed by the NYSDOH under Article 28 of the NYS Public Health Law; and

- Applicant has submitted **Attachment 1 - Statement of Assurances** signed by the Chief Executive Officer (CEO) or Designee to certify the organization meets all criteria listed on **Attachment 1**.

B. Preference Factors

Preference will be given to applicants that demonstrate the following:

- A minimum of five (5) years of experience delivering HCV medical care, treatment, and supportive services within a primary care setting;
- Has at least one provider qualified under the Drug Addiction Treatment Act of 2000 (DATA 2000) to prescribe medication for addiction treatment (MAT) onsite, such as buprenorphine/suboxone or methadone; and
- Has at least one peer certified through the [NYSDOH AI Peer Certification Program](#) in the HCV and/or harm reduction tracks.

III. PROJECT NARRATIVE/WORK PLAN OUTCOMES

A. Program Model Description

Funding through this RFA will support Article 28 health care facilities in Central New York and Long Island to develop primary care-based integrated models of HCV care and treatment that will: 1) increase the number of people living with HCV who are linked to care; 2) increase HCV treatment initiation and completion rates; and 3) increase the number of people cured of HCV.

This will be accomplished by conducting targeted outreach and recruitment, linkage and care coordination to assist people with HCV and HIV/HCV in accessing timely HCV medical care and appropriate supportive services delivered by a multidisciplinary team in a primary care setting. Programs are expected to serve all people with HCV in an equitable manner, with attention to ensuring non-discriminatory care to those currently underserved and socially disadvantaged.

Priority Population: The priority populations for this RFA are people with mono-infection of HCV and/or co-infection of HIV/HCV. This includes uninsured persons.

Successful applicants will demonstrate their ability to:

- Outreach, recruit, and link people living with HCV to care and services;
- Provide care coordination to assess and address issues impacting care;
- Provide comprehensive, high quality HCV medical care, treatment, and peer-delivered supportive services to all people with HCV;
- Provide services that are culturally responsive, trauma informed, and free of stigma and discrimination;

- Design a program that addresses the social determinants of health that impact access to HCV care and completion of treatment (see **Plan to Address Social Determinants of Health - Attachment 2**);
- Prescribe MAT (Medication for Addiction Treatment); and
- Involve people with lived experience of HCV in the planning and design of the proposed program.

Anticipated Outcomes

Funded applicants are expected to achieve the following outcomes:

- Increase the number of people living with HCV who are linked to care;
- Increase HCV treatment initiation and completion rates; and
- Increase the number of people who are cured of HCV.

Performance Indicators

The following performance indicators will be monitored by the NYSDOH AI and reported by funded applicants on a quarterly basis.

Performance Indicator	Target
Proportion of people living with HCV who are linked to HCV care	80%
Proportion of patients who initiate HCV treatment	60%
Proportion of patients who complete HCV treatment	80%
Proportion of patients who are cured	>90%

B. Requirements for the Program

Funded applicants will be expected to provide the following services:

1. **HCV education and risk reduction:** Funded applicants must provide HCV education and risk reduction services with people at risk for or living with HCV. These may include short-term individual or group activities to increase client knowledge of and participation in their health care, address secondary prevention, improve health and decrease the risk of disease transmission. Education must address HCV disease, prevention, testing, treatment and treatment adherence, harm reduction/risk reduction, re-infection, and health promotion.
2. **Targeted outreach and client recruitment:** Funded applicants must develop a plan for identifying and recruiting people with HCV into the program (**HCV Outreach and Recruitment Plan - Attachment 3**). Programs must use available qualitative and quantitative data to target populations known to be at risk for HCV, and to design and

conduct outreach activities at times and in places where there is a high probability of reaching priority populations. Funded applicants must actively seek out referrals from organizations serving people at risk for HCV, including drug treatment programs, state or local correctional facilities, and community-based organizations, such as syringe exchange programs and drug user health hubs. Programs must have a formal linkage agreement with at least one OASAS licensed drug treatment program. Outreach activities will aid in linking and retaining clients in care and may include provision of off-site HCV rapid antibody testing and education; escorting patients from the community to clinic; and building and maintaining positive working linkage relationships with partner organizations.

3. **HCV care coordination:** Funded applicants must facilitate health systems navigation and provide patient support for adherence to HCV care and treatment by assessing obstacles and addressing unmet needs that would prevent clients from effectively engaging and remaining in care and initiating and completing HCV treatment. Programs must develop and implement a proactive plan that minimizes these obstacles and supports improvement of self-sufficiency skills. The plan must identify the providers, programs or partner agencies involved and their respective roles in the client's care, as well as mechanisms to ensure information exchange across care interfaces. Funded applicants must have a plan for referrals for services not available onsite. Care coordination activities include linkage to care activities, assistance addressing social determinants of health impacting HCV care, and treatment adherence services.
4. **HCV care and treatment:** Funded applicants must provide HCV care and treatment in accordance with NYSDOH AI or nationally recognized clinical guidelines. These guidelines can be found on the following websites: <http://www.hivguidelines.org/hcv-infection/treatment-with-daa/> and <https://www.hevguidelines.org/contents>. Funded applicants must integrate HCV treatment adherence services into the routine delivery of care to ensure adherence to and completion of HCV treatment. Funded applicants must have a memorandum of understanding (MOU) with a liver specialist for consultation and referrals for clients with decompensated cirrhosis or other complex conditions.
5. **Medication for addiction treatment:** MAT is an effective tool for the management of opioid dependence. MAT is also an effective HCV prevention intervention by reducing the frequency of injecting. MAT is also safe and effective when used in conjunction with HCV treatment. Funded applicants must have a plan to prescribe buprenorphine or methadone onsite. If MAT is not being prescribed at the time of contract execution, the program must have a plan for offering this service by the end of the contract's first year.
6. **HCV peer-delivered interventions:** Funded applicants must have a plan to provide interventions delivered by peers – persons with shared lived experience in HCV. Peer interventions may include: targeted outreach and recruitment, client escort, appointment reminders, treatment adherence, HCV education, and other supportive services.

Funded applicants will also be required to:

7. Participate in the Hepatitis C Assistance Program (HepCAP). HepCAP was established by the NYSDOH AI to assist uninsured persons with HCV in obtaining necessary medical care and treatment. It does not cover the cost of HCV medications. Programs are

reimbursed through HepCAP for services provided to uninsured HCV mono-infected persons to establish the state of HCV disease and monitor HCV treatment, including laboratory testing.

8. Ensure on-going HCV education and training for clinical and non-clinical staff. Staff education and training must address HCV disease, prevention, testing, treatment and treatment adherence, harm reduction/risk reduction, and re-infection. Additionally, clinical and non-clinical staff must be prepared to respond to an opioid overdose at the clinic. Staff training must reflect use of a trauma-informed and harm reduction approach to address the ways identity, culture, community, and oppression can affect a person's experience of stigma, access to supports and resources, and opportunities for safety. Education and training resources are available through the NYSDOH AI for funded contractors at: <https://www.health.ny.gov/diseases/aids/general/about/education.htm>
9. Adhere to Health Literacy Universal Precautions (<https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/index.html>)
10. Demonstrate Cultural Responsiveness and Linguistic Competency: Access to quality health care should be a basic right for any person, regardless of their culture, language or risk-related behavior. Stigma, especially as it relates to drug use and mental health, continues to be a significant and pervasive barrier which impairs access to quality prevention and health care services for patients living with or at risk for HCV. Stigma can also have an adverse impact on HIV and HCV treatment uptake, treatment adherence, and quality of life. To effectively engage and provide high-quality services, a meaningful, trusting partnership should be developed between provider and client. Programs should be designed with an understanding of the differences that derive from language, culture, race/ethnicity, religion, age, and developmental characteristics.
11. Apply a trauma-informed approach. Trauma and adversity affect a person's physical and mental well-being and can influence how they respond to the environment, relationships, interventions, and treatment services. A trauma-informed approach acknowledges the prevalence of trauma; recognizes how trauma affects all individuals involved with the program and organization, including its own workforce; and responds by proactively resisting re-traumatization. Trauma-informed care applies a universal precautions approach based on five guiding values and principles: Safety, Trustworthiness, Choice, Collaboration, and Empowerment to avoid re-traumatization. Additional resources on a trauma informed approach are available through the [Institute on Trauma and Trauma-Informed Care \(ITTIC\)](#) at the University of Buffalo and in [SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach](#).
12. Adhere to all objectives, tasks, and performance measures as listed in the **Care and Treatment Program Work Plan - Attachment 4**.
13. Ensure that accurate and current policies and procedures for the HCV program are in place that address the following program components: outreach and recruitment protocol; program eligibility/enrollment; peer services; client appointment follow-up; client referrals and follow-up; HIPAA confidentiality; staff time and effort; equipment; materials review; case conferencing; support services; client complaints; case closure;

third party reimbursement; and client incentives. Written policies and procedures are to be reviewed and updated at least annually.

14. Participate in a collaborative process with the NYSDOH AI to assess program outcomes. This will be accomplished by providing monthly narrative reports, conducting ongoing continuous quality improvement activities, attending quarterly provider calls, and participating in one annual in-person provider meeting. Programs are expected to describe their progress with respect to: 1) program implementation; 2) client recruitment; 3) success in meeting the work plan objectives and performance measures (**Care and Treatment Program Work Plan - Attachment 4.**); 4) significant accomplishments achieved; and 5) barriers encountered and plans to address noted problems.
15. Participate in the NYS HCV quality of care program - eHEPQUAL. eHEPQUAL is a web-based application designed to capture data and generate reports that enable the health care provider to assess the quality of care provided to patients living with HCV. Annually, programs are expected to submit data on key quality of care indicators defined by the NYSDOH AI, Quality of Care Advisory Committee.
16. Submit statistical reports on clients served and other data using the AIDS Institute Reporting System (AIRS). Successful applicants must demonstrate the personnel and hardware related capacity to collect and report all required data using AIRS. Details on this software product may be obtained by accessing the following internet address, www.airсны.org.

IV. ADMINISTRATIVE REQUIREMENTS

A. Issuing Agency

This RFA is issued by the NYSDOH AI, Division of HIV and Hepatitis Health Care, Bureau of Hepatitis Health Care, and Health Research, Inc. The Department and HRI are responsible for the requirements specified herein and for the evaluation of all applications.

B. Question and Answer Phase

All substantive questions must be submitted to Colleen Flanigan via email to:

hepatabc@health.ny.gov

To the degree possible, each inquiry should cite the RFA section and paragraph to which it refers. **Written questions will be accepted until the date posted on the cover of this RFA.** Questions of a technical nature can also be addressed in writing at the email address listed above. **Questions are of a technical nature if they are limited to how to prepare your application (e.g., formatting) rather than relating to the substance of the application.**

All questions submitted should state “Eliminating Hepatitis C by Improving Access to Hepatitis C Care and Treatment – Central New York and Long Island Regions” in the subject line.

Prospective applicants should note that all clarifications and exceptions, including those relating to the terms and conditions of the contract, are to be raised prior to the submission of an application.

The RFA has been posted on HRI's public website at: <http://www.healthresearch.org/funding-opportunities>.

Questions and answers, as well as any updates and/or modifications, will also be posted on these websites. All such updates will be posted on or about the date identified on the cover sheet of this RFA.

C. Letter of Intent

Letters of intent are not a requirement of this RFA.

D. Applicant Conference

An applicant conference will not be held for this project.

E. How to File an Application

Applicants must submit one PDF version of the entire application (including Application Cover Page, Application checklist, narrative and all attachments) to AIGPU@health.ny.gov by 4:00 pm ET on the date posted on the cover page of this RFA. The subject of the email line should reference *Eliminating Hepatitis C by Improving Access to Hepatitis C Care and Treatment — Central New York and Long Island Regions*.

*It is the applicant's responsibility to see that applications are emailed to AIGPU@health.ny.gov by 4:00 PM ET on the date specified. **Late applications will not be accepted.**

F. Department of Health's and HRI's Reserved Rights

The Department of Health and HRI reserve the right to:

1. Reject any or all applications received in response to this RFA.
2. Withdraw the RFA at any time, at the Department's or HRI's sole discretion.
3. Make an award under the RFA in whole or in part.
4. Disqualify any applicant whose conduct and/or proposal fails to conform to the requirements of the RFA.
5. Seek clarifications and revisions of applications.
6. Use application information obtained through site visits, management interviews and the state's investigation of an applicant's qualifications, experience, ability or financial standing, and any material or information submitted by the applicant in response to the agency's request for clarifying information in the course of evaluation and/or selection under the RFA.

7. Prior to application opening, amend the RFA specifications to correct errors or oversights, or to supply additional information, as it becomes available.
8. Prior to application opening, direct applicants to submit proposal modifications addressing subsequent RFA amendments.
9. Change any of the scheduled dates.
10. Waive any requirements that are not material.
11. Award more than one contract resulting from this RFA.
12. Conduct contract negotiations with the next responsible applicant, should the Department or HRI be unsuccessful in negotiating with the selected applicant.
13. Utilize any and all ideas submitted with the applications received.
14. Unless otherwise specified in the RFA, every offer is firm and not revocable for a period of 60 days from the bid opening.
15. Waive or modify minor irregularities in applications received after prior notification to the applicant.
16. Require clarification at any time during the procurement process and/or require correction of arithmetic or other apparent errors for the purpose of assuring a full and complete understanding of an offeror's application and/or to determine an offeror's compliance with the requirements of the RFA.
17. Negotiate with successful applicants within the scope of the RFA in the best interests of the State or HRI.
18. Eliminate any mandatory, non-material specifications that cannot be complied with by all applicants.
19. Award grants based on geographic or regional considerations to serve the best interests of the State or HRI.

G. Term of Contract

Any contract resulting from this RFA will be effective only upon approval by HRI. Refer to **Attachment 5 – HRI General Terms and Conditions**.

Contracts resulting from this RFA will be for 12-month terms. The anticipated start date of the contracts is October 1, 2021. However, depending on the funding source, the initial contract term could be for a shorter time period. HRI awards may be renewed for up to four (4) additional annual contract periods based on satisfactory performance and availability of funds. HRI reserves the right to revise the award amount as necessary due to changes in the availability of funding.

H. Payment & Reporting Requirements of Grant Awardees

1. Due to requirements of the federal funder, no advance payments will be allowed for HRI contracts resulting from this procurement.

2. The funded contractor will be expected to submit voucher claims and reports of expenditures in the manner that HRI requires. Required forms will be provided with the contract package.

All payments and reporting requirements will be detailed in Exhibit “C” of the final contract.

I. General Specifications

- 1) By signing **Attachment 6 (Application Cover Page)** each applicant attests to its express authority to sign on behalf of the applicant.
- 2) Contractors will possess, at no cost to the State or HRI, all qualifications, licenses and permits to engage in the required business as may be required within the jurisdiction where the work specified is to be performed. Workers to be employed in the performance of this contract will possess the qualifications, training, licenses and permits as may be required within such jurisdiction.
- 3) Submission of an application indicates the applicant's acceptance of all conditions and terms contained in this RFA, including the terms and conditions of the contract. Any exceptions allowed by HRI and the Department during the Question and Answer Phase (Section IV.B.) must be clearly noted in Attachment 6 (Application Cover Page).
- 4) An applicant may be disqualified from receiving awards if such applicant or any subsidiary, affiliate, partner, officer, agent or principal thereof, or anyone in its employ, has previously failed to perform satisfactorily in connection with public bidding or contracts.
- 5) Provisions Upon Default
 - a. The services to be performed by the Applicant shall be at all times subject to the direction and control of the Department and HRI as to all matters arising in connection with or relating to the contract resulting from this RFA.
 - b. In the event that the Applicant, through any cause, fails to perform any of the terms, covenants or promises of any contract resulting from this RFA, the Department acting for and on behalf of the State and HRI, shall thereupon have the right to terminate the contract by giving notice in writing of the fact and date of such termination to the Applicant.
 - c. If, in the judgement of the Department, the Applicant acts in such a way which is likely to or does impair or prejudice the interests of the State, the Department acting on behalf of the State and HRI, shall thereupon have the right to terminate any contract resulting from this RFA by giving notice in writing of the fact and date of such termination to the Contractor. In such case, the Contractor shall receive equitable compensation for such services as shall, in the judgement of the State Comptroller, have been satisfactorily performed by the Contractor up to the date of the termination of this agreement, which such compensation shall not exceed the total cost incurred for the work which the Contractor was engaged in at the time of such termination, subject to audit by the State Comptroller.

- 1) Applicant must maintain an active registration in the System for Award Management (SAM) at SAM.gov, have no exclusions or delinquent federal debt.

V. COMPLETING THE APPLICATION

A. Application Format and Content

Please respond to each of the following statements and questions. Your responses comprise your application. ***Number/letter your narrative to correspond to each statement and question in the order presented below.*** Be specific and complete in your response. Indicate if the statement or question is not relevant to your agency or proposal. The value assigned to each section is an indication of the relative weight that will be given to that section when your application is scored.

An applicant checklist has been included to help ensure that submission requirements have been met. Applicants should review this attachment before and after writing the application. **In assembling your application, please follow the outline provided in the Application Checklist (Attachment 7).**

Applications should not exceed fifteen (15) double-spaced pages, (not including the budget, and all attachments) using a 12-pitch type font with one-inch margins on all sides. Pages should be numbered consecutively, including all attachments. The **Application Cover Page (Attachment 6)**, Program Abstract, budget and budget justification, and all attachments are **not included** in the 15-page limitation. Please submit only requested information in attachments and do not add attachments that are not requested. **Failure to follow these guidelines will result in a deduction of up to ten (10) points.** When responding to the statements and questions, be mindful that application reviewers may not be familiar with the agency and its services. Therefore, answers should be specific, succinct and responsive to the statements and questions as outlined.

Application Format

1. Program Abstract	Not Scored
2. Preference Factors	Maximum Additional: 3 points
3. Community and Agency Description	Maximum Score: 20 points
4. Program Design and Implementation	Maximum Score: 60 points
5. Budget and Justification	Maximum Score: <u>20 points</u>
	103 points

1. Program Abstract

Not Scored

Maximum one page (*Not counted in page total*)

- 1a) Applicants should provide a program abstract. The abstract must contain a summary of the proposed program, including how it will meet the anticipated outcomes of this RFA.

2. Preference Factors

Maximum 2 Pages

Maximum Additional: 3 Points

- 2a) Provide information to demonstrate that your organization has a minimum of five (5) years of experience delivering HCV medical care, treatment, and supportive services within a primary care setting.
- 2b) Provide information to demonstrate that at least one provider involved with the program is qualified under the Drug Addiction Treatment Act of 2000 (DATA 2000) to prescribe MAT onsite, such as buprenorphine/suboxone or methadone.
- 2c) Provide information to demonstrate that at least one peer is certified through the NYSDOH AI Peer Certification Program in the HCV and/or harm reduction tracks.

3. Community and Agency Description

Maximum 3 Pages

Maximum Score: 20 points

- 3a) Describe why your organization is qualified to implement the proposed primary care-based integrated model of HCV care and treatment. Include both qualitative and quantitative evidence to address this question.
- 3b) What are the other programs and agencies in the geographic area that are relevant to your proposed program model and describe how your organization will leverage these programs to maximize benefit to your priority population(s) without supplanting other resources?
- 3c) Describe any existing grants your organization receives, including those from the NYSDOH AI that are relevant to this proposal. Include the results of the program and successes of those grants. Applicants are required to complete **Funding History for Hepatitis C-Related Services (Attachment 8)**.

4. Program Design and Implementation

Maximum 10 Pages

Maximum Score: 60 points

- 4a) Briefly describe your organization's primary care-based integrated model of HCV care and treatment. Describe how your agency will provide onsite HCV core services outlined in Section. III, B. - Requirements for the Program. Include the geographic area to be served. Include a timeline for implementation of the program. Applicants are required to complete **HCV Site(s), Address, Day(s) and Hours of Operation - Attachment 9 AND Timeline for Care and Treatment Program Implementation - Attachment 10**.
- 4b) Provide your service projections in **Hepatitis C Care Cascade Projections of Services - Attachment 11**.
- 4c) Describe how your program will outreach and recruit people with HCV into the care and

treatment program, including where you anticipate conducting outreach, when, and who will perform outreach. Applicants are required to complete **HCV Outreach and Recruitment Plan - Attachment 3**. Please describe your plan for monitoring the effectiveness of your targeted outreach and recruitment plan and making any necessary adjustments. Include any **Memorandums of Understanding (MOUs) with community partners as Attachment 12** for partners your program anticipates collaborating with for outreach and recruitment.

- 4d) Describe the strategies your program will use to work effectively with at least one drug treatment program in the area. Include any **MOUs with drug treatment program partners as Attachment 13**.
- 4e) Describe how your program will assess social and structural barriers people with HCV face when accessing HCV care and treatment. Applicants are required to indicate how their program will address each of the five key areas of social determinants of health by completing **Plan to Address Social Determinants of Health - Attachment 2**.
- 4f) Describe how your program will ensure effective care coordination across the HCV care continuum including linkage to care, facilitation of health systems navigation and patient adherence support. Describe how you will ensure information exchange across care interfaces. Describe the plan for referral of clients for services that cannot be offered onsite by your program, including referrals internal and external to your agency. Describe how these referrals will be tracked. Applicants are required to include any **MOUs with community partners** to provide services not available through the program as **Attachment 12**.
- 4g) Describe how your program will provide HCV education and risk reduction services with people at risk for, living with, and cured from HCV.
- 4h) Describe your plan to provide quality HCV care, treatment and supportive services, including who will provide these services, their experience and credentials. Describe your relationship with a liver specialist for referral of clients with decompensated cirrhosis or other complex conditions. Describe strategies to ensure adherence to and completion of HCV treatment, including assessment of SVR. Applicants are required to include any **MOUs with liver specialists as Attachment 14**.
- 4i) Describe how your program will provide trauma-informed, culturally responsive, stigma-free affirming services.
- 4j) Describe how your program will provide MAT. If not currently prescribing MAT, describe your plan for ensuring it is offered by the end of the first year of the contract.
- 4k) Describe the proposed staffing pattern for the key core services of the program. Provide a brief description of each position's roles and responsibilities, along with job qualifications, educational background, licensures and experience required. Applicants are required to complete **Agency Capacity and Staffing Information - Attachment 15**.

If in-kind staff are included in the proposed program, they should be included and identified as such.

- 4l) Describe the plan to ensure on-going HCV education and training to clinical and non-clinical staff.
- 4m) Describe how peers will be utilized in your program. Specify whether peers will be certified through the NYSDOH AI Peer Certification Program.
- 4n) Describe how your program will provide continuous monitoring and evaluation of the proposed program activities. Describe the involvement of people with lived experience of HCV.
- 4o) Describe how data will flow from point of service delivery to entry into AIRS. Include how your organization will collect, analyze and report client level and programmatic data across the HCV care continuum.

5. Budget and Justification

Maximum one page (*Not counted in page total*)

Maximum Score: 20 points

Complete and submit a budget following these instructions:

- 5a) Applicants are instructed to prepare an annual budget based on the maximum award as listed for the region in which they are applying. Complete all required Budget Pages. See **Attachment 16 - HRI Expenditure Based Budget Summary**. Instructions for completing the budget forms are included as **Attachment 17 – Guide for Completing HRI Budget Forms**. All budget lines should be calculated as whole dollar amounts. All costs should be related to the proposed activities, as described in the application narrative and work plan, and should be justified in detail. All costs should be reasonable and cost-effective. Contracts established resulting from the RFA will be cost reimbursable.
- 5b) For staff listed in the Personal services (Salary and Fringe) section of the budget, include a breakdown of the total salary needs for staff. Indicate how the positions relate to program implementation. Applicants are instructed to include a justification for each of the requested FTEs and for the fringe benefits requested. The budget justifications should delineate how the percentage of staff time devoted to this initiative has been determined. **The percent of effort allowed for billable staff must not exceed 20% cumulative, meaning the combined percent of effort for all billable staff positions cannot exceed 20%.**
- 5c) For each item listed under Non-Personal services, describe how it is necessary for program implementation. Non-Personal services include: Contractual, Travel, Equipment, Space/Property & Utilities, Operating Expenses, and Miscellaneous costs. The budget should include all subcontracts/consultants with contractual amounts and methodologies. **The annual budget should include travel for at least one HCV care and treatment clinician to attend a national conference on topics related to HCV care and treatment.**

5d) For the last three (3) years, does your organization's Statement of Activities from your yearly audit show that revenues exceeded expenses or expenses exceeded revenue? If the expenses exceeded revenues, please describe both the cost reduction plan and the deficit reduction plan that will correct this. Applicants are required to submit the **Statement of Activities** from your yearly audit for the last three (3) years as **Attachment 18**. The Statement of Activities must show total support and revenue and total expenditures.

5e) Applicants are required to submit a copy of their organization Time and Effort policy as **Attachment 19**.

5f) Describe the specific internal controls your agency uses to comply with the Federal Uniform Guidance (2 CFR 200).

5g) Funding requests must adhere to the following guidelines:

- An indirect cost rate of up to 10% of total modified direct costs can be requested. If your organization has a federally approved rate, an indirect cost rate of up to 20% of total direct costs can be requested. If your agency has a federally approved rate of less than 20%, the maximum indirect rate that can be requested is the federally approved rate.
- Funding may only be used to expand existing activities and create new activities pursuant to this RFA. Funds may **not** be used to supplant funds for currently existing staff and activities. Agencies currently funded by the NYSDOH AI to provide program services in accordance with the requirements of this RFA must apply for continuation of funding.
- Ineligible budget items will be removed from the budget prior to contracting. Ineligible items are those items determined by NYSDOH/HRI to be inadequately justified in relation to the proposed program or not fundable under existing federal guidance (Uniform Guidance). The budget amount requested will be reduced to reflect the removal of the ineligible items.

It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared and submitted.

B. Freedom of Information Law

All applications may be disclosed or used by NYSDOH to the extent permitted by law. NYSDOH may disclose an application to any person for the purpose of assisting in evaluating the application or for any other lawful purpose. All applications will become State agency records, which will be available to the public in accordance with the Freedom of Information Law. **Any portion of the application that an applicant believes constitutes proprietary information entitled to confidential handling, as an exception to the Freedom of Information Law, must be clearly and specifically designated in the application.** If NYSDOH agrees with the proprietary claim, the designated portion of the application will be withheld from public disclosure. Blanket assertions of proprietary material will not be accepted, and failure to specifically designate proprietary material may be deemed a waiver of any right to confidential handling of such material.

C. Review & Award Process

Applications meeting the eligibility requirements and guidelines set forth above will be reviewed and evaluated competitively by a panel convened by the NYSDOH AI using an objective rating system reflective of the required items specified for each component.

NYSDOH AI and HRI anticipate that there may be more worthy applications than can be funded with available resources. Please see Section I. B of the RFA for specific review and award information. Applications will be deemed to fall into one of three categories: 1) approved and funded, 2) not funded, due to limited resources, and 3) not approved.

In cases in which two or more applicants for funding are judged on the basis of their written applications to be equal in quality, the applicant with the highest score for Section 3 – Program Design and Implementation will receive the award.

Applications with minor issues (missing information that is not essential to timely review and would not impact review scores) MAY be processed, at the discretion of NYSDOH AI and HRI, but all issues need to be resolved prior to time of award. An application with unresolved issues at the time award recommendations are made will be determined to be non-responsive and will be disqualified.

NYSDOH AI and HRI reserve the right to revise the award amounts as necessary due to changes in the availability of funding. If changes in funding amounts are necessary for this initiative, funding will be modified and awarded in the same manner as outlined in the award process described above. NYSDOH AI and HRI reserve the right to review and rescind all subcontracts.

Once the awards have been made, applicants may request a debriefing of their application (whether their application was funded or not funded). Please note the debriefing will be limited only to the strengths and weaknesses of the subject application and will not include any discussion of other applications. Requests must be received no later than fifteen (15) calendar days from date of award or non-award announcement.

To request a debriefing, please send an email to Colleen Flanigan at hepatabc@health.ny.gov. In the subject line, please write: *Debriefing request Eliminating Hepatitis C by Improving Access to Hepatitis C Care and Treatment – Central New York and Long Island Regions.*

In the event unsuccessful applicants wish to protest the award resulting from this RFA, applicants should follow the protest procedures established by the Office of the State Comptroller (OSC). These procedures can be found on the OSC website at <http://www.osc.state.ny.us/agencies/guide/MyWebHelp>. (Section XI. 17.)

VI. ATTACHMENTS

Attachment 1: Statement of Assurances*

Attachment 2: Plan to Address Social Determinants of Health*

Attachment 3: HCV Outreach and Recruitment Plan*

Attachment 4: Care and Treatment Program Work Plan**

Attachment 5: HRI General Terms and Conditions**

Attachment 6: Application Cover Page*

Attachment 7: Application Checklist*

Attachment 8: Funding for Hepatitis C-Related Services*

Attachment 9: HCV Site(s), Address, Day(s) and Hours of Operation*

Attachment 10: Timeline for Care and Treatment Program Implementation*

Attachment 11: Hepatitis C Care Cascade Projections of Services*

Attachment 12: Memorandums of Understanding – Community Partners*

Attachment 13: Memorandums of Understanding – Drug Treatment Program Partners*

Attachment 14: Memorandums of Understanding – Liver Specialists*

Attachment 15: Agency Capacity and Staffing Information*

Attachment 16: HRI Expenditure Based Budget Summary*

Attachment 17: Guide for completing HRI budget forms**

Attachment 18: Statement of Activities for past three (3) years*

Attachment 19: Organization Time & Effort Policy*

***These attachments are required and must be submitted with your application.**

****These attachments are attached to the RFA and are for applicant information only. These attachments do not need to be completed.**

ATTACHMENT 4 – WORK PLAN

SUMMARY

PROJECT NAME: Eliminating Hepatitis C by Improving Access to Hepatitis C Care and Treatment – Central New York and Long Island Regions

Provide an overview of the project including goals, tasks, desired outcomes and performance measures:

The intent of this initiative is to support primary care-based integrated models of HCV care and treatment within Article 28 health care facilities that will: 1) increase the number of people living with HCV who are linked to care; 2) increase HCV treatment initiation and completion rates; and 3) increase the number of people cured of HCV.

This will be accomplished by conducting targeted outreach and recruitment, linkage and care coordination to assist people with HCV and HIV/HCV in accessing timely HCV medical care and appropriate supportive services delivered by a multidisciplinary team in a primary care setting. Programs are expected to serve all people with HCV in an equitable manner, with attention to ensuring non-discriminatory care to those currently underserved and socially disadvantaged.

Funded applicants will be held to the Objective, Tasks and Performance Measures as listed in Attachment 4: Work Plan.

ATTACHMENT 4 – WORK PLAN

DETAIL

OBJECTIVE	TASKS	PERFORMANCE MEASURES
1 - Increase hepatitis C awareness and knowledge	1.1 HCV education, training and materials are available to ALL clients. Each will address HCV disease, prevention, testing, treatments, harm reduction/risk reduction, reinfection and health promotion.	1.1.1 HCV educational materials are readily available.
	1.2 Provide HCV education and coaching with people at risk for or living with HCV.	1.2.1. Monthly narrative reports document activities relating to HCV education and coaching.
	1.3 Conduct health promotion and HCV risk reduction activities to promote liver wellness and prevent reinfection.	1.3.1. Monthly narrative reports document activities relating to HCV health promotion and HCV risk reduction.
	1.4 Ensure HCV providers and staff receive HCV training. Trainings should address advances in HCV prevention, testing, treatment, harm reduction and reinfection prevention.	1.4.1 Copies of staff training certificates, or a list of staff training attended by program staff is maintained.
	1.5 Promote AIDS Institute trainings on HCV, drug user health, harm reduction widely across the agency.	1.5.1 N/A

OBJECTIVE	TASKS	PERFORMANCE MEASURES
2 - Increase the number of persons with HCV who are linked to care.	2.1. Hire and maintain staff , preferably with lived experience of HCV, to conduct outreach and recruitment activities.	2.1.1 Outreach staff are hired and maintained throughout the contract period.
	2.2. Develop, implement and monitor a client outreach and recruitment plan that is responsive to the needs of the population.	2.2.1 A written outreach and recruitment plan is developed, reviewed and revised at least annually.
	2.3. Develop a strategy for promoting the HCV program within the local community.	2.3.1 Projected client enrollment targets increase annually by 10%.
	2.4. Collaborate with organizations serving people at risk for or living with HCV and promote the program among them.	2.4.1 Written linkage agreements are in place with organizations serving individuals at risk for or living with HCV.
	2.5. Program staff are trained on motivational interviewing techniques.	2.5.1 Copies of staff training certificates, or a list of staff training attended by program staff is maintained.
	2.6. Document all client outreach and recruitment activities in AIRS.	2.6.1. Data is entered into AIRS monthly.

OBJECTIVE	TASKS	PERFORMANCE MEASURES
3 - Ensure efficient, effective care coordination across the HCV care continuum	3.1 Hire and maintain staff to conduct care coordination activities.	3.1.1 Staff who conduct care coordination activities are hired and maintained throughout the contract period.
	3.2 Conduct assessment of social determinants of health and needs with all clients.	3.2.1 Assessment tool addresses the five key areas of social determinants of health.
		3.2.2 100% of clients enrolled in the program completed an assessment of social determinants of health.
	3.3 Develop, implement and monitor a care coordination plan that addresses clients' specific needs, social determinants of health, and supports improvement of self-sufficiency skills.	3.3.1 100% of clients enrolled in the program will have a care coordination plan.
		3.3.2 The care coordination plan documents linkage and navigation activities.
		3.3.3 The care coordination plan documents coordination with other service providers (mental health services, substance use services, harm reduction services including opioid overdose prevention, etc.).
		3.3.4 The care coordination plan documents assistance with health benefits, financial assistance, transportation, housing and employment as needed.
		3.3.5 The care coordination plan documents support for adherence to appointments, including escorts to referral appointments as needed.
		3.3.6 The care coordination plan documents social support as needed.
3.3.7 The care coordination plan documents coordination of referral appointments for medical and non-medical services.		

		3.3.8. 80% of the clients enrolled in the program are linked to the HCV provider.
3.4	Ensure information exchange across care interfaces , including tracking of referrals for services not available within the program.	3.4.1 Agency has a policy and procedure for tracking referrals for services that is reviewed annually.
		3.4.2 At least one multi-disciplinary case conference will be held and documented for all clients within 6 months of enrollment.
3.5	Develop and maintain relationships with community referral resources to address client needs.	3.5.1 Written linkage agreements are available for all offsite services.
3.6	Document all care coordination activities in AIRS.	3.6.1. Data is entered into AIRS monthly.

OBJECTIVE	TASKS	PERFORMANCE MEASURES
4 - Increase the number of people who start & complete treatment and are cured.	4.1 Provide comprehensive HCV care and treatment in accordance with state and/or national guidelines.	4.1.1 60% of clients linked to care will initiate treatment.
	4.2 Provide HCV care and treatment services using a multidisciplinary team approach.	4.2.1 N/A
	4.3 Assess for HCV treatment readiness and adherence , prior to treatment initiation, including alcohol counseling and mental health assessment.	4.3.1 100% of clients linked to care are assessed for treatment readiness.
	4.4 Establish systems for prior authorization.	4.4.1 N/A
	4.5 Employ HCV treatment adherence strategies to ensure adherence to and completion of HCV treatment.	4.5.1 80% of clients who initiate treatment will complete HCV treatment.
	4.6 Employ strategies to ensure adherence to provider appointments.	4.6.1 N/A
	4.7 Employ strategies to ensure final assessment of SVR.	4.7.1. >90% of clients finishing treatment complete the final assessment of SVR.
		4.7.2. >90% of clients who complete treatment are cured.
	4.8 Ensure and maintain HCV providers' knowledge and understanding of HCV clinical guidelines.	4.8.1 One provider will attend the AASLD conference each year of the contract period.
	4.9 Establish and maintain collaborations with a liver specialist.	4.9.1 A subcontract or MOU is established and maintained with a liver specialist.
	4.10 Establish and maintain collaborations with other providers to address co-morbidities.	4.10.1 N/A
4.11 Document all HCV care and treatment activities in the patient medical record and in AIRS.	4.11.1. Data is entered into AIRS monthly.	

OBJECTIVE	TASKS	PERFORMANCE MEASURES
5 - Ensure access to medication for addiction treatment (MAT)	5.1 Establish and maintain MAT prescribing on-site in accordance with federal and NYS regulations.	5.1.1 At least one MAT prescriber is employed by the program during the contract period.
	5.2 Provide education on MAT.	5.2.1 N/A
	5.3 Document all MAT activities in the patient medical record and in AIRS.	5.3.1. Data is entered into AIRS monthly.
6- Ensure the availability of peer-delivered interventions and services	6.1 Ensure the availability of peer-delivered services across the care continuum from client recruitment to cure.	6.1.1 At least one peer will be employed by the program during the contract period.
	6.2 Ensure a plan is in place for peer recruitment, training, supervision and evaluation of peers and the peer-delivered services.	6.2.1 N/A
	6.3 Promote the AIDS Institute Peer Certification Program and support peer staff in pursuing certification.	6.3.1 N/A
	6.4 Document all peer interventions in AIRS.	6.4.1. Data is entered into AIRS monthly.

OBJECTIVE	TASKS	PERFORMANCE MEASURES
7- Maintain a stigma-free program responsive to the needs of people with HCV	7.1 Establish and maintain a non-discriminatory and stigma-free environment.	7.1.1 Agency has policies in place to recognize the signs of stigma, respond to incidence of discrimination and avoid inadvertently re-stigmatizing people who use drugs.
	7.2 Culturally and linguistically appropriate client education materials are available.	7.2.1 N/A
	7.3 Linguistically appropriate services are provided by certified interpreters or bilingual staff during regular hours of operation at no cost to the client.	7.3.1 N/A
	7.4 Program clients are involved in program design, implementation and evaluation.	7.4.1 Clients are afforded opportunities to provide input into the HCV care and treatment model.
	7.5 Provide a mechanism for clients to provide feedback on service planning, delivery and quality.	7.5.1 N/A
	7.6 Staff are trained on the principles of harm reduction.	7.6.1 Copies of staff training certificates, or a list of staff training attended by program staff is maintained.
	7.7 Staff are trained on the principles of trauma-informed care.	7.7.1 Copies of staff training certificates, or a list of staff training attended by program staff is maintained.
	7.8 Training on health literacy and effective communication is provided for staff initially and on an as-needed basis thereafter.	7.8.1 Copies of staff training certificates, or a list of staff training attended by program staff is maintained.

OBJECTIVE	TASKS	PERFORMANCE MEASURES
8- Establish and maintain a system for data collection and reporting.	8.1 Implement the AIRS system.	8.1.1 AIRS extracts are submitted in a timely manner.
	8.2 Ensure systems are in place to collect and report data across the HCV care continuum.	8.2.1 AIRS data reports are reviewed by program staff at least quarterly to ensure accuracy and completeness.
9- Engage in continuous quality improvement	9.1 Routinely examine agency data as it relates to program goals and workplan performance measures.	9.1.1 N/A
	9.2 Develop and implement CQI activities to improve areas of deficiency.	9.2.1 Summarize CQI activities in monthly narrative, including identified areas in need of improvement, steps taken to improve and resulting outcomes
	9.3 Participate in initiative-related meetings and calls with the AI.	9.3.1 Program staff attend quarterly program calls.
		9.3.2 Program attendance at one annual in-person provider meeting.

OBJECTIVE	TASKS	PERFORMANCE MEASURES
<p>10- Establish and maintain a policies and procedures manual for the HCV program</p>	<p>10.1. Ensure that accurate and current policies and procedures are in place that address each of the key HCV program components.</p>	<p>10.1.1. Outreach and recruitment protocol is established, reviewed and updated at least annually.</p>
		<p>10.1.2. Written policies and procedures for Program Eligibility/Enrollment are established, reviewed and updated at least annually.</p>
		<p>10.1.3. Written policies and procedures for Peer Services are established, reviewed and updated at least annually.</p>
		<p>10.1.4. Written policies and procedures for Client Appointment Follow-up are established, reviewed and updated at least annually.</p>
		<p>10.1.5. Written policies and procedures for Client Referrals and Follow-up are established, reviewed and updated at least annually.</p>
		<p>10.1.6. Written policies and procedures for HIPAA Confidentiality are established, reviewed and updated at least annually.</p>
		<p>10.1.7. Written policies and procedures for Time and Effort are established, reviewed and updated at least annually.</p>
		<p>10.1.8. Written policies and procedures for Equipment are established, reviewed and updated at least annually.</p>
		<p>10.1.9. Written policies and procedures for Materials Review are established, reviewed and updated at least annually.</p>
		<p>10.1.10. Written policies and procedures for Case Conferencing are established, reviewed and updated at least annually.</p>
		<p>10.1.11. Written policies and procedures for Support Services are established, reviewed and updated at least annually.</p>

		10.1.12. Written policies and procedures for Client Complaints are established, reviewed and updated at least annually.
		10.1.13. Written policies and procedures for Case Closure are established, reviewed and updated at least annually.
		10.1.14. Written policies and procedures for Third Party Revenue Reimbursement are established, reviewed and updated at least annually.
		10.1.15. Written policies and procedures for Client Incentives are established, reviewed and updated at least annually.
OBJECTIVE	TASKS	PERFORMANCE MEASURES
11- Flexibility in programming for directing resources effectively	11.1 Flexibility in programming is necessary to ensure that resources are effectively directed to the populations and communities most in need.	11.1.1 N/A
	11.2 Contract activities & deliverables may be modified at any point in this contract upon direction of the AIDS Institute to address emerging needs or disparities , emerging HIV/STD/HCV epidemiologic patterns, or to accommodate advances in best practice.	11.2.1 Aid with non-workplan public health issues if/when they arise.
	11.3 Assist with other priority public health issues if/when they arise (e.g., local STD case increases, outbreaks, emergency situations, etc.). The contract manager must approve non-workplan work.	11.3.1 Aid with non-workplan public health issues if/when they arise.

Attachment 5
General Terms and Conditions - Health Research Incorporated Contracts

1. **Term** - This Agreement shall be effective and allowable costs may be incurred by the Contractor from the Contract Start Date through the Contract End Date, (hereinafter, the "Term") unless terminated sooner as hereinafter provided or extended by mutual agreement of the parties.
2. **Allowable Costs/Contract Amount –**
 - a) In consideration of the Contractor's performance under this Agreement, HRI shall reimburse the Contractor for allowable costs incurred in performing the Scope of Work, which is attached hereto as Exhibit A, in accordance with the terms and subject to the limits of this Agreement.
 - b) It is expressly understood and agreed that the aggregate of all allowable costs under the Agreement shall in no event exceed the Total Contract Amount, except upon formal amendment of this Agreement as provided herein below.
 - c) The allowable cost of performing the work under this Agreement shall be the costs approved in the Budget attached hereto as Exhibit B and actually incurred by the Contractor, either directly incident or properly allocable, to the Agreement, in the performance of the Scope of Work. For work performed under a Scope of Work that results from a federally funded grant or contract, Contractor's costs must be in accordance with cost principles of the Department of Health and Human Services Grants Policy Statement (HHS GPS). To be allowable, a cost must be reasonable, necessary, and cost-effective (as reasonably determined by HRI). In calculating costs, the accounting practices of Contractor must be based on generally accepted accounting principles and practices appropriate to the circumstances and consistent with other comparable activities of Contractor. Costs resulting from inconsistent practices in excess of the amount that would have resulted from using practices consistent with this Section 2(c) are unallowable. Contractor shall supply documentation of such policies and procedures to HRI when requested.
 - d) Irrespective of whether the "Audit Requirements" specified in paragraph 3(a) are applicable to this Agreement, all accounts and records of cost relating to this Agreement shall be subject to audit by HRI or its duly authorized representative(s) and/or the Project Sponsor during the Term and for three years after the final voucher is submitted for payment. This provision includes the right for HRI to request copies of source documentation in support of any costs claimed. If an audit is started before the expiration of the 3-year period, the records must be retained until all findings involving the records have been resolved and final action taken. Any reimbursement made by HRI under this Agreement shall be subject to retroactive correction and adjustment upon such audits. The Contractor agrees to repay HRI promptly any amount(s) determined on audit to have been incorrectly paid. HRI retains the right, to the extent not prohibited by law or its agreements with the applicable Project Sponsor(s) to recoup any amounts required to be repaid by the Contractor to HRI by offsetting those amounts against amounts due to the Contractor from HRI pursuant to this or other agreements. The Contractor shall maintain appropriate and complete accounts, records, documents, and other evidence showing the support for all costs incurred under this Agreement.
3. **Administrative, Financial and Audit Regulations –**
 - a) This Agreement shall be audited, administered, and allowable costs shall be determined in accordance with the terms of this Agreement and the requirements and principles applicable to the Contractor as noted below, including, but not limited to, the Office of Management and Budget (OMB) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (referred to herein as the "Uniform Guidance") as codified in Title 2 of the Code of Federal Regulations. The federal regulations specified below apply to the Contractor (excepting the "Audit Requirements," which apply to federally- funded projects only), regardless of the source of the funding specified (federal/non-federal) on the face page of this Agreement. For non-federally funded projects any right granted by the regulation to the federal sponsor shall be deemed granted to the Project Sponsor. It is understood that a Project Sponsor may impose restrictions/requirements beyond those noted below in which case such restrictions/requirements will be noted in Attachment B Program Specific Clauses.

Contractor Type	Administrative Requirements	Cost Principles	Audit Requirements Federally Funded Only
College or University	Uniform Guidance	Uniform Guidance	Uniform Guidance
Not-for-Profit	Uniform Guidance	Uniform Guidance	Uniform Guidance

State, Local Gov. or Indian Tribe	Uniform Guidance	Uniform Guidance	Uniform Guidance
For-Profit	45 CFR Part 74	48 CFR Part 31.2	Uniform Guidance
Hospitals	2 CFR Part 215	45 CFR Part 74	Uniform Guidance

a) If this Agreement is federally funded, the Contractor will provide copies of audit reports required under any of the above audit requirements to HRI within 30 days after completion of the audit.

2. Payments -

- a) No payments will be made by HRI until such time as HRI is in receipt of the following items:
- Insurance Certificates pursuant to Article 9;
 - A copy of the Contractor's latest audited financial statements (including management letter if requested);
 - A copy of the Contractor's most recent 990 or Corporate Tax Return;
 - A copy of the Contractor's approved federal indirect cost rate(s) and fringe benefit rate (the "federal rates"); or documentation (which is acceptable to HRI) which shows the Contractor's methodology for allocating these costs to this Agreement. If, at any time during the Term the federal rates are lower than those approved for this Agreement, the rates applicable to this Agreement will be reduced to the federal rates;
 - A copy of the Contractor's time and effort reporting system procedures (which are compliant with the Uniform Guidance) if salaries and wages are approved in the Budget.
 - A copy of equipment policy if equipment is in the approved budget.
 - Further documentation as requested by HRI to establish the Contractor's fiscal and programmatic capability to perform under this Agreement.

Unless and until the above items are submitted to and accepted by HRI, the Contractor will incur otherwise allowable costs at its own risk and without agreement that such costs will be reimbursed by HRI pursuant to the terms of this Agreement. No payments, which would otherwise be due under this Agreement, will be due by HRI until such time, if ever, as the above items are submitted to and accepted by HRI.

- b) The Contractor shall submit voucher claims and reports of expenditures at the Required Voucher Frequency noted on the face page of this Agreement, in such form and manner, as HRI shall require. HRI will reimburse Contractor upon receipt of expense vouchers pursuant to the Budget in Exhibit B, so long as Contractor has adhered to all the terms of this Agreement and provided the reimbursement is not disallowed or disallowable under the terms of this Agreement. All information required on the voucher must be provided or HRI may pay or disallow the costs at its discretion. HRI reserves the right to request additional back up documentation on any voucher submitted. Further, all vouchers must be received within thirty (30) days of the end of each period defined as the Required Voucher Frequency (i.e. each month, each quarter). Contractor shall submit a final voucher designated by the Contractor as the "Completion Voucher" no later than sixty (60) days from termination of the Agreement. Vouchers received after the 60 day period may be paid or disallowed at the discretion of HRI.
- c) The Contractor agrees that if it shall receive or accrue any refunds, rebates, credits or other amounts (including any interest thereon) that relate to costs for which the Contractor has been reimbursed by HRI under this Agreement it shall notify HRI of that fact and shall pay or, where appropriate, credit HRI those amounts.
- d) The Contractor represents, warrants and certifies that reimbursement claimed by the Contractor under this Agreement shall not duplicate reimbursement received from other sources, including, but not limited to client fees, private insurance, public donations, grants, legislative funding from units of government, or any other source. The terms of this paragraph shall be deemed continuing representations upon which HRI has relied in entering into and which are the essences of its agreements herein.

3. Termination - Either party may terminate this Agreement with or without cause at any time by giving thirty (30) days written notice to the other party. HRI may terminate this Agreement immediately upon written notice to the Contractor in the event of a material breach of this Agreement by the Contractor. It is understood and agreed, however, that in the event that Contractor is in default upon any of its obligations hereunder at the time of any termination, such right of termination shall be in addition to any other rights or remedies which HRI may have against Contractor by reason of such default. Upon termination of the Agreement by either party for any reason, Contractor shall immediately turn over to HRI any works in progress, materials, and deliverables (whether completed or not) related to the services performed up to the date of termination.

4. Representations and Warranties – Contractor represents and warrants that:

- a) it has the full right and authority to enter into and perform under this Agreement;

- a) it will perform the services set forth in Exhibit A in a workmanlike manner consistent with applicable industry practices;
 - b) the services, work products, and deliverables provided by Contractor will conform to the specifications in Exhibit A;
 - c) there is no pending or threatened claim or litigation that would have a material adverse impact on its ability to perform as required by this Agreement.
- 2. Indemnity** - To the fullest extent permitted by law, Contractor shall indemnify, hold harmless and defend HRI, its agents, employees, officers, board members, the New York State Department of Health, and the People of the State of New York against all claims, damages, losses or expenses including but not limited to attorneys' fees arising out of or resulting from the performance of the agreement, provided any such claim, damage, loss or expense arises out of, or in connection with, any act or omission by Contractor, or anyone directly or indirectly employed or contracted by Contractor, in the performance of services under this Agreement, and such acts or omissions (i) constitute negligence, willful misconduct, or fraud; (ii) are attributable to bodily injury, sickness, disease or death, or to injury to or destruction of tangible property, including loss of use resulting there from; (iii) cause the breach of any confidentiality obligations set forth herein; (iv) relate to any claim for compensation and payment by any employee or agent of Contractor; (v) result in intellectual property infringement or misappropriation by Contractor, its employees, agents, or subcontractors; or (vi) are violations of regulatory or statutory provisions of the New York State Labor Law, OSHA or other governing rule or applicable law. The obligation of the Contractor to indemnify any party under this paragraph shall not be limited in any manner by any limitation of the amount of insurance coverage or benefits including workers' compensation or other employee benefit acts provided by the Contractor. In all subcontracts entered into by the Contractor related to performance under this Agreement, the Contractor will include a provision requiring the subcontractor to provide the same indemnity and hold harmless to the indemnified parties specified in this paragraph.
- 3. Amendments/Budget Changes –**
- a) This Agreement may be changed, amended, modified or extended only by mutual consent of the parties provided that such consent shall be in writing and executed by the parties hereto prior to the time such change shall take effect, with the exception of changes and amendments that are made mandatory by the Project Sponsor under the sponsoring grant/contract, which will take effect in accordance with the Project Sponsor's requirements and schedule.
 - b) In no event shall there be expenses charged to a restricted budget category without prior written consent of HRI.
 - c) The Budget Flexibility Percentage indicates the percent change allowable in each category of the Budget, with the exception of a restricted budget category. As with any desired change to this Agreement, budget category deviations exceeding the Budget Flexibility Percentage in any category of the Budget are not permitted unless approved in writing by HRI. In no way shall the Budget Flexibility Percentage be construed to allow the Contractor to exceed the Total Contract Amount less the restricted budget line, nor shall it be construed to permit charging of any unallowable expense to any budget category. An otherwise allowable charge is disallowed if the charge amount plus any Budget Flexibility Percentage exceeds the amount of the budget category for that cost.
- 4. Insurance –**
- a) The Contractor shall maintain or cause to be maintained, throughout the Term, insurance or self-insurance equivalents of the types and in the amounts specified in section b) below. Certificates of Insurance shall evidence all such insurance. It is expressly understood that the coverage's and limits referred to herein shall not in any way limit the liability of the Contractor. The Contractor shall include a provision in all subcontracts requiring the subcontractor to maintain the same types and amounts of insurance specified in b) below.
 - b) The Contractor shall purchase and maintain at a minimum the following types of insurance coverage and limits of liability:
 - 1) Commercial General Liability (CGL) with limits of insurance of not less than \$1,000,000 each Occurrence and \$2,000,000 Annual Aggregate. If the CGL coverage contains a General Aggregate Limit, such General Aggregate shall apply separately to each project. HRI and the People of the State of New York shall be included as Additional Insureds on the Contractor's CGL, using ISO Additional Insured Endorsement CG 20 10 11 85 or an endorsement providing equivalent coverage to the Additional Insureds. The CGL insurance for the Additional Insureds shall be as broad as the coverage provided for the Named Insured Contractor. It shall apply as primary and non-contributing insurance before any insurance maintained by the Additional Insureds.
 - 2) Business Automobile Liability (AL) with limits of insurance of not less than \$1,000,000 each accident. AL coverage must include coverage for liability arising out of all owned, leased, hired and non-owned automobiles.

- 1) Workers Compensation (WC) & Employers Liability (EL) with limits of insurance of not less than \$100,000 each accident for bodily injury by accident and \$100,000 each employee for injury by disease.
 - 2) If specified by HRI, Professional Liability Insurance with limits of liability of \$1,000,000 each occurrence and \$3,000,000 aggregate.
- a) Provide that such policy may not be canceled or modified until at least 30 days after receipt by HRI of written notice thereof; and
 - b) Be reasonably satisfactory to HRI in all other respects.

2. Publications and Conferences –

- a) All written materials, publications, journal articles, audio-visuals that are either presentations of, or products of the Scope of Work which are authorized for publication or public dissemination, subject to the confidentiality restrictions herein, will acknowledge HRI, the New York State Department of Health (DOH) and the Project Sponsor and will specifically reference the Sponsor Reference Number as the contract/grant funding the work with a disclaimer, as appropriate, such as: “The content of this publication (journal article, etc.) is solely the responsibility of the authors and does not necessarily represent the official views of HRI or the Project Sponsor. This requirement shall be in addition to any publication requirements or provisions specified in Attachment B – Program Specific Clauses.
- b) Conference Disclaimer: Where a conference is funded by a grant, cooperative agreement, sub-grant and/or a contract the recipient must include the following statement on conference materials, including promotional materials, agenda, and Internet sites, “Funding for this conference was made possible (in part) by the <insert Project Sponsor name>. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of HRI, NYS Department of Health or the Project Sponsor, nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.”

Use of Logos: In order to avoid confusion as to the conference source or a false appearance of Government, HRI or DOH endorsement, the Project Sponsor, HRI and/or DOH’s logos may not be used on conference materials without the advance, express written consent of the Project Sponsor, HRI and/or DOH.

3. Title -

- a) Unless noted otherwise in an attachment to this Agreement, title to all equipment purchased by the Contractor with funds from this Agreement will remain with Contractor. Notwithstanding the foregoing, at any point during the Term or within 180 days after the expiration of the Term, HRI may require, upon written notice to the Contractor, that the Contractor transfer title to some or all of such equipment to HRI. The Contractor agrees to expeditiously take all required actions to effect such transfer of title to HRI when so requested. In addition to any requirements or limitations imposed upon the Contractor pursuant to paragraph 3 hereof, during the Term and for the 180 day period after expiration of the Term, the Contractor shall not transfer, convey, sublet, hire, lien, grant a security interest in, encumber or dispose of any such equipment. The provisions of this paragraph shall survive the termination of this Agreement.
- b) Contractor acknowledges and agrees that all work products, deliverables, designs, writings, inventions, discoveries, and related materials (collectively, “Works”) made, produced or delivered by Contractor in the performance of its obligations hereunder will be owned exclusively by HRI. All copyrightable Works are “works made for hire”, which are owned by HRI. Contractor will assign, and hereby assigns and transfers to HRI, all intellectual property rights in and to Works, including without limitation, copyrights, patent rights, trademark rights, and trade secret rights. The Contractor shall take all steps necessary to effect the transfer of the rights granted in this paragraph to HRI. As set forth in paragraph 18(d) herein, Standard Patent Rights Clauses under the Bayh-Dole Act (37 C.F.R. 401) are hereby incorporated by reference and shall supersede any terms in this Agreement that may conflict therewith. The provisions of this paragraph shall survive the termination of this Agreement.

4. Confidentiality - Information relating to individuals who may receive services pursuant to this Agreement shall be maintained and used only for the purposes intended under the Agreement and in conformity with applicable provisions of laws and regulations or specified in Attachment B, Program Specific Clauses. Contractor acknowledges and agrees that, during the course of performing services under this Agreement, it may receive information of a confidential nature, whether marked or unmarked, (“Confidential Information”). Contractor agrees to protect such Confidential Information with the same degree of care it uses to protect its own confidential information of a similar nature and importance, but with no less than reasonable care. Contractor will not use Confidential Information for any purpose other than to facilitate the

provision of services under this Agreement, and Contractor will not disclose Confidential Information in an unauthorized manner to any third party without HRI's advance written consent.

1. Equal Opportunity and Non-Discrimination - Contractor acknowledges and agrees, whether or not required by Article 15 of the New York State Executive Law (also known as the Human Rights Law) or any other State or Federal statutory or constitutional non-discrimination provisions, that Contractor will not discriminate against any employee or applicant for employment because of race, color, creed, religion, sex, sexual orientation, gender identity, national origin, age, disability, pregnancy-related condition, military or veteran status, genetic predisposition or carrier status, marital or familial status, domestic violence victim status, individual's relationship or association with a member of a protected category or any other basis protected by applicable state and federal law. Furthermore, Contractor agrees that neither it nor its authorized subcontractors, if any, shall, by reason of race, color, creed, religion, sex, sexual orientation, gender identity, national origin, age, disability, pregnancy-related condition, military or veteran status, genetic predisposition or carrier status, marital or familial status, domestic violence victim status, individual's relationship or association with a member of a protected category or any other basis protected by applicable state and federal law: (a) discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the performance of work under this Agreement. Contractor is subject to fines of \$50.00 per person per day for any violation of this provision, or of Section 220-e or Section 239 of the New York State Labor Law, as well as possible termination of this Agreement and forfeiture of all moneys due hereunder for a second or subsequent violation.

2. Use of Names - Unless otherwise specifically provided for in Attachment B, Program Specific Clauses, and excepting the acknowledgment of sponsorship of this work as required in paragraph 10 hereof (Publications), the Contractor will not use the names of Health Research, Inc. the New York State Department of Health, the State of New York or any employees or officials of these entities without the express written approval of HRI.

3. Site Visits and Reporting Requirements -

- a) Contractor shall establish and maintain complete and accurate books, records, documents, accounts and other evidence directly pertinent to performance of the services under this Agreement (collectively, "Records"). The Records must be kept for three years after the final voucher is paid.
- b) HRI and the Project Sponsor or their designee(s) shall have the right to conduct site visits where services are performed and observe the services being performed by the Contractor and any subcontractor and inspect Records. The Contractor shall render all assistance and cooperation to HRI and the Project Sponsor in connection with such visits. The surveyors shall have the authority, to the extent designated by HRI, for determining contract compliance as well as the quality of services being provided.
- c) The Contractor agrees to provide the HRI Project Director, or his or her designee complete reports, including but not limited to, narrative and statistical reports relating to the project's activities and progress at the Reporting Frequency specified in Exhibit C. The format of such reports will be determined by the HRI Project Director and conveyed in writing to the Contractor.

4. Miscellaneous –

- a) Contractor and any subcontractors are independent contractors, not partners, joint venturers, or agents of HRI, the New York State Department of Health or the Project Sponsor; nor are the Contractor's or subcontractor's employees considered employees of HRI, the New York State Department of Health or the Project Sponsor for any reason. Contractor shall pay employee compensation, fringe benefits, disability benefits, workers compensation and/or withholding and other applicable taxes (collectively the "Employers Obligations") when due. The contractor shall include in all subcontracts a provisions requiring the subcontractor to pay its Employer Obligations when due. Contractor is fully responsible for the performance of any independent contractors or subcontractors.
- b) This Agreement may not be assigned by the Contractor or its right, title or interest therein assigned, transferred, conveyed, sublet, subjected to any security interest or encumbrance of any type, or disposed of without the previous consent, in writing, of HRI.
- c) This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.
- d) Contractor shall have no interest, financial or otherwise, direct or indirect, or engage in any business, transaction, or professional activity, that may create a conflict, or the appearance of a conflict, with the proper discharge of Contractor's duties under this Agreement or the conflict of interest policy of any agency providing federal funding under this Agreement. In the event any actual or potential conflict arises, Contractor agrees to notify HRI in writing

within ten (10) days to allow HRI to evaluate any potential or actual conflict. Contractor certifies that it has implemented and is in compliance with a financial conflict of interest policy that complies with 42 CFR Part 50 Subpart F, as may be amended from time to time. Contractor acknowledges that it cannot engage in any work or receive funding from HRI until they have disclosed all financial conflicts of interest and identified an acceptable management strategy to HRI. At HRI's request, Contractor will provide information about how it identified, managed, reduced or eliminated conflicts of interest. Failure to disclose such conflicts or to provide information to HRI may be cause for termination as specified in the Terms & Conditions of this Agreement. HRI shall provide Contractor with a copy of notifications sent to the funding agency under this Agreement.

- a) Regardless of the place of physical execution or performance, this Agreement shall be construed according to the laws of the State of New York and shall be deemed to have been executed in the State of New York. Any action to enforce, arising out of or relating in any way to any of the provisions of this Agreement may only be brought and prosecuted in such court or courts located in the State of New York as provided by law; and the parties' consent to the jurisdiction of said court or courts located in the State of New York and to venue in and for the County of Albany to the exclusion of all other court(s) and to service of process by certified or registered mail, postage prepaid, return receipt requested, or by any other manner provided by law. The provisions of this paragraph shall survive the termination of this Agreement.
- b) All official notices to any party relating to material terms hereunder shall be in writing, signed by the party giving it, and shall be sufficiently given or served only if sent by registered mail, return receipt requested, addressed to the parties at their addresses indicated on the face page of this Agreement.
- c) If any provision of this Agreement or any provision of any document, attachment or Exhibit attached hereto or incorporated herein by reference shall be held invalid, such invalidity shall not affect the other provisions of this Agreement but this Agreement shall be reformed and construed as if such invalid provision had never been contained herein and such provision reformed so that it would be valid, operative and enforceable to the maximum extent permitted.
- d) The failure of HRI to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right by HRI or excuse a similar subsequent failure to perform any such term or condition by Contractor.
- e) It is understood that the functions to be performed by the Contractor pursuant to this Agreement are non-sectarian in nature. The Contractor agrees that the functions shall be performed in a manner that does not discriminate on the basis of religious belief and that neither promotes nor discourages adherence to particular religious beliefs or to religion in general.
- f) In the performance of the work authorized pursuant to this Agreement, Contractor agrees to comply with all applicable project sponsor, federal, state and municipal laws, rules, ordinances, regulations, guidelines, and requirements governing or affecting the performance under this Agreement in addition to those specifically included in the Agreement and its incorporated Exhibits and Attachments.
- g) This Agreement may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Delivery of an executed signature page to the Agreement by facsimile transmission or PDF shall be as effective as delivery of a manually signed counterpart.
- h) The following pertains only to Contractors located in New York City or doing business in New York City: Contractor agrees it is compliant with NYC Local Law 96 (2018) Stop Sexual Harassment in NYC Act.

2. Federal Regulations/Requirements Applicable to All HRI Agreements -

The following are federal regulations, which apply to all Agreements; regardless of the source of the funding (federal/non-federal) specified on the face page of this Agreement. Accordingly, regardless of the funding source, the Contractor agrees to abide by the following:

- a) Human Subjects, Derived Materials or Data - If human subjects are used in the conduct of the work supported by this Agreement, the Contractor agrees to comply with the applicable federal laws, regulations, and policy statements issued by DHHS in effect at the time the work is conducted, including but not limited to Section 474(a) of the HHS Act, implemented by 45 CFR Part 46 as amended or updated. The Contractor further agrees to complete an OMB No. 0990-0263 form on an annual basis.
- b) Laboratory Animals - If vertebrate animals are used in the conduct of the work supported by this Agreement, the Contractor shall comply with the Laboratory Animal Welfare Act of 1966, as amended (7 USC 2131 et. seq.) and the regulations promulgated thereunder by the Secretary of Agriculture pertaining to the care, handling and

treatment of vertebrate animals held or used in research supported by Federal funds. The Contractor will comply with the *HHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions* and the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training*.

- a) Research Involving Recombinant DNA Molecules - The Contractor and its respective principle investigators or research administrators must comply with the most recent *Public Health Service Guidelines for Research Involving Recombinant DNA Molecules* published at Federal Register 46266 or such later revision of those guidelines as may be published in the Federal Register as well as current *NIH Guidelines for Research Involving Recombinant DNA Molecules*.
- b) Contractor is required to register with SAM.gov and maintain active status as stated in 2 CFR Subtitle A, Chapter 1, and Part 25. Contractor must maintain the accuracy/currency of the information in SAM at all times during which the Contractor has an active agreement with HRI. Additionally, the Contractor is required to review and update the information at least annually after the initial registration, and more frequently if required by changes in information.
- c) Equal Employment Opportunity – for all agreements

This contractor and subcontractor shall abide by the requirements of 41 CFR 60-1.4(a) which is hereby incorporated herein.

This contractor and subcontractor shall abide by the requirements of 41 CFR 60-741.5(a). This regulation prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified individuals with disabilities.

This contractor and subcontractor shall abide by the requirements of 41 CFR 60-300.5(a). This regulation prohibits discrimination against qualified protected veterans, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified protected veterans.

- d) National Labor Relations Act (Executive Order 13496)

Contractors that are not exempt from the National Labor Relations Act and have contracts, subcontracts or purchase orders subject to EO 13496 must satisfy the requirements of that Executive Order and its implementing regulations at 29 CFR Part 471 to be in compliance with the law.

2. Federal Regulations/Requirements Applicable to Federally Funded Agreements through HRI -

The following clauses are applicable only for Agreements that are specified as federally funded on the Agreement face page:

- a) If the Project Sponsor is an agency of the Department of Health and Human Services: The Contractor must be in compliance with the following Department of Health and Human Services and Public Health Service regulations implementing the statutes referenced below and assures that, where applicable, it has a valid assurance (HHS-690) concerning the following on file with the Office of Civil Rights, Office of the Secretary, HHS.
 - 1) Title VI of the Civil Rights Act of 1964 as implemented in 45 CFR Part 80.
 - 2) Section 504 of the Rehabilitation Act of 1973, as amended, as implemented by 45 CFR Part 84.
 - 3) The Age Discrimination Act of 1975 (P.L. 94-135) as amended, as implemented by 45 CFR 1.
 - 4) Title IX of the Education Amendments of 1972, in particular section 901 as implemented at 45 CFR Part 86 (elimination of sex discrimination).
 - 5) Sections 522 and 526 of the HHS Act as amended, implemented at 45 CFR Part 84 (non-discrimination for drug/alcohol abusers in admission or treatment).
 - 6) Section 543 of the HHS Act as amended as implemented at 42 CFR Part 2 (confidentiality of records of substance abuse patients).
 - 7) Trafficking in Persons – subject to the requirement of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104).
 - 8) HHS regulatory requirements on Responsibility of Applicants for Promoting Objectivity in Research and financial conflicts of interest set forth in 42 C.F.R Parts 50 and 94.
 - 9) Contractor agrees to comply with other requirements of the Project Sponsor, if applicable, set forth in the HHS Grants Policy Statement.

- a) Notice as Required Under Public Law 103-333: If the Project Sponsor is an agency of the Department of Health and Human Services, the Contractor is hereby notified of the following statement made by the Congress at Section 507(a) of Public Law 103-333 (The DHHS Appropriations Act, 1995, hereinafter the "Act"): It is the sense of the Congress that, to the greatest extent practicable, all equipment and products purchased with funds made available in this Act should be American-made.
- b) Contractor agrees that if the Project Sponsor is other than an agency of the DHHS, items 1, 2, 3 and 4 in subsection a) above shall be complied with as implemented by the Project Sponsor.
- c) Contractor agrees that the Standard Patent Rights Clauses under the Bayh-Dole Act (37 C.F.R 401) are hereby incorporated by reference and shall supersede any terms in this Agreement that may conflict therewith.
- d) Criminal Penalties for Acts Involving Federal Health Care Programs - Recipients and sub-recipients of Federal funds are subject to the strictures of 42 U.S.C. 1320A-7B(b)) and should be cognizant of the risk of criminal and administrative liability under this statute, including for making false statements and representations and illegal remunerations.
- e) Equipment and Products - To the greatest extent practicable, all equipment and products purchased with federal funds should be American-made.
- f) Acknowledgment of Federal Support – When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part by federal money, all awardees receiving Federal funds, including and not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.
- g) Recipients and sub-recipients of Federal funds are subject to the strictures of the Medicare and Medicaid anti-kickback statute (42. U.S.C. 1320a-7b (b) and should be cognizant of the risk of criminal and administrative liability under this statute, specifically under 42 U.S.C. 1320 7b(b) illegal remunerations which states, in part, that whoever knowingly and willfully: (A) Solicits or receives (or offers or pays) any remuneration (including kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring (or to induce such person to refer) and individual to a person for the furnishing or arranging for the furnishing of any item or service, OR (B) in return for purchasing, leasing, ordering, or recommending purchasing, leasing, or ordering, or to purchase, lease, or order, any goods, facility, services, or item for which payment may be made in whole or in part under subchapter XIII of this chapter or a State health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years or both.
- h) Clean Air Act and the Federal Water Pollution Control Act Compliance - If this contract is in excess of \$150,000, Contractor agrees to comply and to require that all subcontractors have complied, where applicable, with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. § 7401-7671q.) and the Federal Water Pollution Control Act as amended (33 U.S.C. §1251-1387). Violations must be reported to the Federal awarding agency and the Regional Office of the Environmental Protection Agency (EPA).
- i) Americans With Disabilities Act - This agreement is subject to the provisions of Subtitle A of Title II of the Americans with Disabilities Act of 1990, 42. U.S.C. 12132 ("ADA") and regulations promulgated pursuant thereto, see 28 CFR Part 35. The Contractor shall not discriminate against an individual with a disability, as defined in the ADA, in providing services, programs or activities pursuant to this Agreement.
- j) Whistleblower Policy: Congress has enacted whistleblower protection statute 41 U.S.C. 4712, which applies to all employees working for contractors, grantees, subcontractors, and subgrantees on federal grants and contracts. This program requires all grantees, subgrantees and subcontractors to: inform their employees working on any federally funded award they are subject to the whistleblower rights and remedies of the program; inform their employee in writing of employee whistleblower protections under 41 U.S.C. 4712 in the predominant native language of the workforce; and Contractors and grantees will include such requirements in any agreement made with a subcontractor or subgrantee.

The statute (41 U.S.C. 4712) states that an "employee of a contractor, subcontractor, grantee [or subgrantee] may not be discharged, demoted, or otherwise discriminated against as a reprisal for "whistleblowing". In addition, whistleblower protections cannot be waived by any agreement, policy, form, or condition of employment.

Whistleblowing is defined as making a disclosure “that the employee reasonably believes is evidence of any of the following: gross mismanagement of a federal contract or grant; a gross waste of federal funds; an abuse of authority relating to a federal contract or grant; a substantial and specific danger to public health or safety; or a violation of law, rule, or regulation related to a federal contract or grant (including the competition for, or negotiation of, a contract or grant). To qualify under the statute, the employee’s disclosure must be made to: a Member of Congress or a representative of a Congressional committee; or an Inspector General; or the Government Accountability Office; or a Federal employee responsible for contract or grant oversight or management at the relevant agency; or an authorized official of the Department of Justice or other law enforcement agency; or a court or grand jury; a management official or other employee of the contractor, subcontractor, grantee or subgrantee who has the responsibility to investigate, discover or address misconduct.

1. Required Federal Certifications –

Acceptance of this Agreement by Contractor constitutes certification by the Contractor of all of the following:

- a) The Contractor is not presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from covered transactions by any Federal department or agency.
- b) The Contractor is not delinquent on any Federal debt.
- c) Byrd Anti-Lobbying Amendment (31 U.S.C. § 1352) – Contracts for \$100,000 or more must file the required certifications. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. § 1352. Each tier must also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the non-Federal award.
- d) The Contractor shall comply with the requirements of the Pro-Children Act of 1994 and shall not allow smoking within any portion of any indoor facility used for the provision of health, day care, early childhood development, education or library services to children under the age of eighteen (18) if the services are funded by a federal program, as this Agreement is, or if the services are provided in indoor facilities that are constructed, operated or maintained with such federal funds.
- e) The Contractor has established administrative policies regarding Scientific Misconduct as required by the Final Rule 42 CFR Part 93, Subpart A as published at the 54 Federal Register 32446, August 8, 1989.
- f) The Contractor maintains a drug free workplace in compliance with the Drug Free Workplace Act of 1988 as implemented in 45 CFR Part 76.
- g) If the Project Sponsor is either an agency of the Public Health Service or the National Science Foundation, the Contractor is in compliance with the rules governing Objectivity in Research as published in 60 Federal Register July 11, 1995.
- h) Compliance with EO13513, Federal Leadership on Reducing Text Messaging while Driving, October 1, 2009. Recipients and sub recipients of CDC grant funds are prohibited both from texting while driving a Government owned vehicle and/or using Government furnished electronic equipment while driving any vehicle. Grant recipients and sub recipients are responsible for ensuring their employees are aware of this prohibition and adhere to this prohibition.
- i) EO 13166, August 11, 2000, requires recipients receiving Federal financial assistance to take steps to ensure that people with limited English proficiency can meaningfully access health and social services. A program of language assistance should provide for effective communication between the service provider and the person with limited English proficiency to facilitate participation in, and meaningful access to, services. The obligations of recipients are explained on the OCR website at <http://www.hhs.gov/sites/default/files/ocr/civilrights/resources/specialtopics/lep/lepguidance.pdf>.
- j) Equal Employment Opportunity, requires compliance with E.O. 13672 "Further Amendments to Executive Order 11478, Equal Employment Opportunity in the Federal Government, and Executive Order 11246, "Equal Employment Opportunity", and as supplemented by regulations at 41 CFR part 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor."

The Contractor shall require that the language of all of the above certifications will be included in the award documents for all subawards under this Agreement (including subcontracts, subgrants, and contracts under grants, loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly. The Contractor agrees to notify HRI immediately if there is a change in its status relating to any of the above certifications.

Attachment 17
INSTRUCTIONS FOR COMPLETION OF BUDGET FORMS FOR SOLICITATIONS

Applicants may access the Excel file to be used for submission of the budget by downloading it at: <http://www.healthresearch.org/funding-opportunities>

Page 1 - Summary Budget

This page is linked to the other pages of the budget. The amount requested for each major category should auto-populate as you complete the budget forms. These include:

1. Salaries
2. Fringe Benefits
3. Supplies
4. Travel
5. Equipment
6. Miscellaneous (includes Space, Telecommunications and Other)
7. Subcontracts/Consultants
8. Indirect Costs

The column labeled Third Party Revenue should only be used if a grant-funded position on this contract generates revenue. Please indicate how the revenue generated by this grant will be used in support of the proposed project. For example, if you have a case manager generating \$10,000 in revenue and the revenue will be used to cover supplies, the \$10,000 should be listed in the supplies line in the Third-Party Revenue column.

Page 2- Salaries

Please include all positions for which you are requesting reimbursement on this page. If you wish to show in-kind positions, they may also be included on this page.

Please note: **The percent of effort allowed for billable staff must not exceed 20% cumulative, meaning the combined percent of effort for all billable staff positions cannot exceed 20%.**

Please refer to the instructions regarding the information required in each column. These instructions are provided at the top of each column. Following is a description of each column in the personal services category:

Column 1: For each position, indicate the title along with the incumbent's name. If a position is vacant, please indicate "TBD" (to be determined).

Column 2: For each position, indicate the number of hours worked per week regardless of funding source.

Column 3: For each position, indicate the total annual salary regardless of funding source.

Columns 4, 5, and 6 request information specific to the proposed program/project.

Column 4: Indicate the number of months or pay periods each position will be budgeted.

Column 5: For each position, indicate the percent effort devoted to the proposed program/project.

Column 6: Indicate the amount of funding requested from the AIDS Institute for each position.

Column 7: If a position is partially supported by third party revenue, the amount of the third-party revenue should be shown in Column 7.

The totals at the bottom of Columns 6 and 7 should be carried forward to page 1 (the Summary Budget).

Page 3 - Fringe Benefits and Position Descriptions

On the top of page 3, please fill in the requested information on fringe benefits based on your latest audited financial statements. Also, please indicate the amount and rate you are requesting for fringe benefits in this proposed budget. If the rate requested in this proposal exceeds the rate in the financial statements, a brief justification should be attached.

The bottom of the page is for position descriptions. For each position, please indicate the title (consistent with the title shown on page 2, personal services) and a brief description of the duties of the position related to the proposed program/project. Additional pages may be attached if necessary.

Page 3A – Additional area for Position Descriptions

Page 4 – **Supplies, Travel and Equipment** - Please refer to the instructions regarding the information required in each section. **The annual budget should include travel for at least one HCV care and treatment clinician to attend a national conference on topics related to HCV care and treatment.**

Page 5 – **Miscellaneous (Telecommunications, Space and Other)** - Please refer to the instructions regarding the information required in each section.

Page 6 –Subcontracts/Consultant/ Indirect Costs

Please indicate any services for which a subcontract or consultant will be used. Include an estimated cost for these services. An indirect cost rate of up to 10% of modified total direct costs can be requested. If your organization has a federally approved rate, an indirect cost rate of up to 20% of total direct costs can be requested. If your agency has a federally approved rate of less than 20%, the maximum indirect rate that can be requested is the federally approved rate.

Page 7 - Budget Justification

Please provide a narrative justification for each item for which you are requesting reimbursement. (Do not include justification for personal services/positions, as the position descriptions on page 3 serve as this justification.) The justification should describe the requested item, the rationale for requesting the item, and how the item will benefit the proposed program/project. **The budget justification should not exceed two-double spaced pages in total.**