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**Relink RFP-CDAF-2025 Application**

**Background**

|  |  |
| --- | --- |
| **Applicant’s Name:** | *Name of individual submitting the application* |
| **Title:** |  |
| **Application Date:** |  |
| **Primary Investigator:** |  |
| **Project Team Members & Role:** |  |
| **Applicant’s Email:** |  |
| **Phone Number:** |  |
| **Organization/Institution/ Department/ Group:** |  |
| **Address:** |  |
| **City:** |  |
| **State:** |  |
| **Web Address:** |  |
| **Tax Status:** | Choose an item.*Please send a copy of your W-9 with your application* |
| **Tax ID Number:** |  |
| **Year of Inception:** |  |
| **Mission Statement:** |  |
| **Organization’s Overview:** |  |

**As part of this project, will you be:**

**(Your responses below will impact whether your proposal is accepted. The preferred response is highlighted in bold.)**

|  |  |  |
| --- | --- | --- |
| Working in Louisiana, Michigan, Minnesota, Missouri, Montana, Oklahoma, Texas, Washington, Puerto Rico, Washington, DC? | [ ]  Yes | [ ]  **No** |
| Willing to have monthly update meetings? | [ ]  **Yes** | [ ]  No |
| Willing to have quarterly web-conference meetings with other grantees to share best practices? | [ ]  **Yes** | [ ]  No |
| Willing to provide quarterly depersonalized data to measure the progress? | [ ]  **Yes** | [ ]  No |
| Willing to coauthor a manuscript to summarize the aggregate key findings (with all other grantees)? | [ ]  **Yes** | [ ]  No |
| Willing to submit an abstract summarizing your key findings and present your data at a conference (if accepted) with travel costs covered by this grant? | [ ]  **Yes** | [ ]  No |

**Your responses below will not impact whether your proposal is accepted.**

|  |  |  |
| --- | --- | --- |
| Focus of your Study: | [ ]  HCV | [ ]  HBV |
| Are you collaborating with a State Health Agency?  | [ ]  Yes | [ ]  No |
| Will you need an IRB approval to start the project?  | [ ]  Yes | [ ]  No |
| Do you use EPIC electronic medical record system to store your patient data? | [ ]  Yes | [ ]  No |
| If no, what system do you use?  |  |
| Do you use REDCap to store and track patient level data? | [ ]  Yes | [ ]  No |
| If not, what platform are you planning to use to keep track of the progress and diagnosed but untreated individuals? |  |
| Do you have a Patient Navigator i.e., someone/ a team in your organization that can contact diagnosed but untreated individuals? | [ ]  Yes | [ ]  No |
| If, yes, do you plan to hire additional Patient Navigators? | [ ]  Yes | [ ]  No |
| If no, how long will it take to hire and train someone/team (in months)? |  |
| How will you contact diagnosed but untreated individuals? (Check all that apply)[ ]  Phone [ ]  Mail [ ]  Text Message [ ]  Social Media [ ]  Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Proposal Details**

**Population Size:** (Provide the total number and diagnosis type for HCV and/or HBV individuals in your registry. If you don’t know, please provide a guestimate. See the Grant Selection Process section of the RFP for how we estimate the number of DBU individuals your organization will link to care.)

|  |  |
| --- | --- |
| Number of diagnosed but untreated HCV-infected individuals in your registry at the time of proposal submission: | A |
| Number of diagnosed HBV-infected individuals in your registry at the time of proposal submission: (should include those being treated): | B |
| Number of HBV individuals already on treatment in your registry at the time of proposal submission: | C |
| *Your primary data source:* | *Number of Diagnosed but Untreated HCV-infected individuals:* | *Number of HBV-infected individuals (Treated and Untreated):*  | *If more than one data source is used, please provide counts for how many individuals come from each data source. Please note that the values in a + b + c + d must equal the value in A, and the values in e + f + g + h must equal the value in B.* |
| [ ]  PCR+  | **a.** | **e.** |
| [ ]  Antibody+  | **b.** | **f.** |
| [ ]  ICD-9/10  | **c.** | **g.** |
| [ ]  Guestimate | **d.** | **h.** |

**Level of Experience:**

|  |  |
| --- | --- |
| **In the past eight years, how many DBU HCV and/or HBV individuals has your organization or site linked to care?** |  |
| **Please describe, if any, your organization’s infrastructural and other resources, programs and mechanisms (e.g., reimbursement schemas for providers, partnerships, financial assistance or support with accessing adequate insurance for infected individuals etc.) designed to ensure successful treatment onset and retention among HCV and/or HBV individuals.** |  |

|  |  |
| --- | --- |
| **Target Population:** (e.g., general, PWID, homeless etc.) |  |
| **What proportion of your target population includes people who actively inject/use drugs?** |  |
| **Setting** (e.g., name of clinic, hospital, communityetc.) |  |
| **Geographical Scope:**(e.g., city/ies, state/s, urban vs. rural etc.) |  |
| **Your Approach:**(in ≤ 500 words) |  |
| **How will you do things differently than what you are doing now?**(in ≤ 250 words) |  |
| **What will your organization do to continue some, or all Relink activities after the grant ends?**(in ≤ 250 words) |  |
| **Data to be Collected:** | To be eligible for participation in the CDAF-Relink Grant program, participants must be willing to provide depersonalized data which allows CDAF to compare performance metrics across grantees and aggregate data (from all grantees) to measure progress toward relinkage goals. See Appendix A for a list of must have data and Appendix B for a list of nice to have data. A [REDCap Data Dictionary](https://github.com/CDAF-RELINK/CDAF-RELINK-HCV-HBV-Data-Dictionary/releases/tag/v2024-07-02) (which can also be used in Excel) is also available. |
| **Inclusion Criteria:** | *(Feel free to override to add your own inclusion criteria. Delete HCV or HBV if focusing on one infection.)** Individuals with a record of positive test results of HCV antibody (0,1), or
* Individuals with a record of positive test results of HCV-RNA (0,1), or
* Individuals who were treated for their HCV infection but have a record of not achieving SVR (0,1), and
* Individuals who were not treated for their HCV infection (0,1).
* Individuals with a record of positive test results of HBV surface antigen (0,1), or
* Individuals with a record of positive test results of HBV-DNA (0,1), or
* Individuals who were treated for their HBV infection but were lost to follow up (0,1), and
* Individuals who did not start treatment for their HBV infection but were lost to follow up (0,1).

*Note:** For immigrant populations, include if HBV surface antigen results > 12 months
* For individuals with a record of positive test results for HBV-DNA, include if:
	+ If DNA test results > 12 months
	+ If DNA test results <12 months but viral load > 2000 IU/ml
 |
| **Staffing Need:** | *(Feel free to override or modify.)** **Primary Investigator –** responsible for the project design, IRB approval (if needed), implementation and timelines.
* **Patient Navigator\* –** Responsible for contacting individuals diagnosed with HCV/ HBV but untreated and linking them back to care.
* **IT Manager –** Responsible for searching the existing electronic medical record systems to find individuals diagnosed with HCV or HBV but untreated. Also, provide intermitted support to generate reports for the registry updated by the patient navigator.
* **Patient Coordinator\*** – Help participants overcome insurance barriers and get access to care. Could be pharmacy techs.
* **Patient Educator\*** – Talks to participants about their viral hepatis infection, why they should seek treatment, risk of liver disease, risk of HCC, any needed of follow ups, etc.

\**Most organizations already have a patient coordinator (e.g., pharmacy tech for patient coordinator) and patient educator. If already in place, please don’t add them to this project.*  |
| **Presentation of Results:** | *(Feel free to override or modify.)*The results of our study will be submitted to the *XYZ* conference scheduled for *[approximate or exact date]*. |
| **Publication Plan:** | *(Feel free to override or modify.)*We will collaborate with CDAF and other collaborators to coauthor a manuscript that will present the aggregate results of the Relink study.We will also plan to separately submit our results as a manuscript and will notify CDAF prior to submission. *(Optional. Delete if it does not apply.)* |
| **Program Duration:** | XYZ months*Use the provided budget and timeline spreadsheet to estimate the duration of the project in months from approval. Include the spreadsheet with your application. Please note that program duration can be no more than 12 months for Round 4.* |
| **Requested Budget:**  | $XYZ.00*(Use the provided budget and timeline spreadsheet to estimate the total budget. Include the spreadsheet with your application. If your institution will cover the costs of a budget item e.g., project staff or conference travel, please state so clearly in your budget. Your total budget should not exceed $250,000.)* |
| **Curriculum Vitae** | Please provide a copy of the primary investigator’s Curriculum Vitae (CV) |

**Application Check List**

[ ]  Reviewed and agree to contract terms.

[ ]  Filled Application. The Application must be returned to us as a Word document, and the Budget and Timeline form as an Excel spreadsheet, or your proposal will be automatically rejected.

[ ]  Copy of W-9 is attached.

[ ]  Copy of the team members’ CV is attached.

[ ]  Attached a copy of the filled (provided) budget and timeline Excel spreadsheet.

**APPENDIX A (Must Have Data)**

**Required CDAF-Relink Data***(This represents the minimum data reportable for participation in the CDAF-Relink program).*

**I. Identifiers**

Record ID (this cannot be a patient ID but could be patient 1, 2, 3…)

Record Creation Date

***II. Demographics***

Age (Calculated from the date of record creation)

Gender

Race

Ethnicity

Language

***III. Disease Status***

HCV RNA positivity (if applicable)

HBV DNA positivity (if applicable)

***IV. Contact and Linkage to Care***

Has the participant asked to not be contacted?

Contact Date

Contact Status (Unreachable , Available, Declined , Relocated, Deceased , Transplanted, Treated & Cured, Too Ill , Left a Message)

Person Contacted (Participant, Proxy, PCP etc.)

Number of contact attempts (per DBU individual)

Number of DBU individuals contacted per navigator per month

Means of Contact (Phone call, In-person visit etc.)

Enrollment Date (Date on which participant consented to enroll in the program)

Was the participant linked to care?

If yes, date of linkage appointment (Date on which participant is to meet with health provider)

If no, why was participant not linked to care?

**Appendix B (Nice to Have Data)**

**Eligible CDAF-Relink Data *(****Please note that these data are nice to have, not required, because all grantees might not collect or be able to share some of this information. We encourage grantees to share these data if they can and their organization permits. If laboratory, appointment, and/or treatment dates cannot be shared, duration to and between dates can be calculated and shared as days, weeks, or months.)*

***I. Demographics***

Country of Birth

Use of Interpreter

Marital Status

Participant Age (Calculated from the date of appointment)

**II. Contact and Linkage to Care**

Where was the participant linked to care?

***III. Laboratory and Other Test Data*** *(Collected after patient is relinked to care. Includes dates associated with each test)*

HCV Viral Load

HBV Viral Load

HCV Antibody

HBV e-Antigen

HBV s-Antigen

ALT

AST

Platelets

Bilirubin

A1C

AFP

HIV Positivity

HDV Positivity

HDV RNA

Liver Stage

Ultrasound Results

Fib-4 Fibrosis Level

Fib-4 Score - Calculated

***IV. HCV Treatment***

Previous HCV Treatment History (i.e., has the participant ever been treated for HCV? CDAF cannot collect data about treatment type.)

Previous HCV Treatment Frequency

Previous HCV Treatment Outcome

Is HCV participant a treatment candidate?

Reason participant is not a Hep C treatment candidate

HCV Prescription Date

Treatment Start Date

Expected Treatment Completion Date

Expected SVR 4 Date

Expected SVR 12 Date

Treatment Completion Date

Treatment Stop Date (only if patient stops early)

Reason participant stopped HCV treatment without completing

***V. HBV Treatment***

Previous HBV Treatment History (i.e., has the participant ever been treated for HBV? CDAF cannot collect data about treatment type.)

Previous HBV Treatment Outcome

Is HBV participant a treatment candidate?

Reason participant is not a Hep B treatment candidate

HBV Prescription Date

HBV Treatment Start Date

HBV Treatment Stop Date (only if patient stops early)

Reason patient stopped HBV treatment prematurely

HBV Treatment Outcome

Was HBV Treatment delayed?

Reason for HBV treatment delay

***VI. Health History and Barriers to Care***

Comorbidities

Substance Use

Mental Health

Insurance status

HCC History

Loss to follow up reason

Barriers

Language Barrier

Transportation or mobility (Access-a-Ride, escort, MetroCard)

No or unreliable phone (Medicaid phone)

Insurance/finances

Memory/cognitive function (extra and/or written reminders)

Treatment adherence (pill calendar or box, frequent on-tx check-ins)

Appointment adherence (extra appointment reminders, escort)

Mental health

Substance use

Unstable housing

Food instability

HCV Knowledge/Fear/Stigma

HBV Knowledge/Fear/Stigma

Social support (peer, support group)

Needs Health Homes referral

Comorbid conditions

Frequent ED or hospital admissions

Work or family obligation

Other

***VII. Use of Services***

Use of patient navigation services

Use of telehealth services

Type of HCV care provider

Last specialty contacted before loss to follow up

Referrals

Incentives