File No. 151186 Committee Item No. 1
Board Item No. 54

COMMITTEE/BOARD OF SUPERVISORS

AGENDA PACKET CONTENTS LIST

Committee: Budget and Finance **Date** December 2, 2015

Board of Supervisors Meeting **Date** December 8, 2015

Cmte	Board	
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OTHER **(Use back side if additional space is needed)**

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Completed by: Victor Young **Date** November 23, 2015
Completed by: VM **Date** 12/3/15

FILE NO. 151186 RESOLUTION NO.

[Accept and Expend Grant - Gilead Sciences, Inc. - Curing HCV in Incarcerated Patients - $517,119.17]

Resolution retroactively authorizing the San Francisco Department of Public Health to accept and expend a grant in the amount of $517,119.17 from Gilead Sciences, Inc., to participate in a program entitled Curing HCV in Incarcerated Patients for the period of October 1, 2015, through March 31, 2017, waiving indirect costs.

WHEREAS, Gilead Sciences, Inc. has agreed to fund Department of Public Health (DPH) in the amount of $517,119.17 for the period of October 1, 2015, through March 31, 2017; and

WHEREAS, As a condition of receiving the grant funds, Gilead Sciences, Inc. requires the City to enter into an agreement (Agreement), a copy of which is on file with the Clerk of the Board of Supervisors in File No. 151186; which is hereby declared to be a part of this Resolution as if set forth fully herein; and

WHEREAS, The purpose of this project will institute a jail-based demonstration project to examine outcomes of enhanced HCV services in two urban jail systems; and

WHEREAS, Services include HCV screening, testing, disclosure, care, and treatment in the jail setting, paired with patient navigation services post-release to ensure adherence, to achieve and sustain an undetectable viral response, and to reduce health disparities, transmission risk, and liver disease; and

WHEREAS, A request for retroactive approval is being sought because Gilead Sciences, Inc. did not finalize the award letter until October 9, 2015, for a project start date of October 1, 2015; and

WHEREAS, Curing HCV in Incarcerated Patients Grant does not allow for indirect costs to maximize use of grant funds on direct services; and

WHEREAS, The grant terms prohibit including indirect costs in the grant budget; now, therefore, be it

RESOLVED, That DPH is hereby authorized to retroactively accept and expend a grant in the amount of $517,119.17 from Gilead Sciences, Inc.; and

FURTHER RESOLVED, That the Board of Supervisors hereby waives inclusion of indirect costs in the grant budget; and, be it

FURTHER RESOLVED, That DPH is hereby authorized to retroactively accept and expend the grant funds pursuant to San Francisco Administrative Code section 10.170-1; and, be it

FURTHER RESOLVED, That the Director of Health is authorized to enter into the Agreement on behalf of the City.

RECOMMENDED:

for

Barbara A. Garcia, MPA
Director of Health

APPROVED:

Office of the Mayor

for Office of the Controller

File Number: _____
(Provided by Clerk of Board of Supervisors)

Grant Resolution Information Form
(Effective July 2011)

Purpose: Accompanies proposed Board of Supervisors resolutions authorizing a Department to accept and expend grant funds.

The following describes the grant referred to in the accompanying resolution:

1. Grant Title: **Curing HCV in Incarcerated Patients (CHIP)**

2. Department: **Department of Public Health**

3. Contact Person: **Kate Monico Klein** Telephone: **415-581-3160**

4. Grant Approval Status (check one):

[X] Approved by funding agency [ ] Not yet approved

5. Amount of Grant Funding Approved or Applied for: **$517,119.17**

6a. Matching Funds Required: **N/A**
b. Source(s) of matching funds (if applicable): **N/A**

7a. Grant Source Agency: **Gilead Sciences, Inc.**
b. Grant Pass-Through Agency (if applicable):

Proposed Grant Project Summary: **Treatment of HCV disease with Harvoni has been demonstrated to achieve sustained virologic response (SVR) as early as 8 to 12 weeks. Curing Hepatitis C in Incarcerated Patients (CHIP) will institute a jail-based demonstration project to examine outcomes of enhanced HCV services in two urban jail systems. Services include HCV screening, testing, disclosure, care, and treatment in the jail setting, paired with patient navigation services post-release to ensure adherence, to achieve and sustain an undetectable viral response, and to reduce health disparities, transmission risk, and liver disease.**

9. Grant Project Schedule, as allowed in approval documents, or as proposed:

Start-Date: **October 1, 2015** End-Date: **March 31, 2017**

10a. Amount budgeted for contractual services: **$517,119.17**

b. Will contractual services be put out to bid? **No**

c. If so, will contract services help to further the goals of the Department's Local Business Enterprise (LBE) requirements?

d. Is this likely to be a one-time or ongoing request for contracting out? **One time**

11a. Does the budget include indirect costs? [ ] Yes [X] No

b1. If yes, how much?
b2. How was the amount calculated?

c1. If no, why are indirect costs not included?
[ ] Not allowed by granting agency [X] To maximize use of grant funds on direct services
[ ] Other (please explain):

c2. If no indirect costs are included, what would have been the indirect costs? **$0**

12. Any other significant grant requirements or comments:
We respectfully request for approval to accept and expend these funds retroactive to October 1, 2015. The grant source agency did not finalize and approve the letter of award until October 9, 2015.

GRANT CODE (Please include Grant Code and Detail in FAMIS): HGCHIP15

****Disability Access Checklist*** (Department must forward a copy of all completed Grant Information Forms to the Mayor's Office of Disability)**

13. This Grant is intended for activities at (check all that apply):

[X] Existing Site(s)	[X] Existing Structure(s)	[X] Existing Program(s) or Service(s)
[ ] Rehabilitated Site(s)	[ ] Rehabilitated Structure(s)	[X] New Program(s) or Service(s)
[ ] New Site(s)	[ ] New Structure(s)	

14. The Departmental ADA Coordinator or the Mayor's Office on Disability have reviewed the proposal and concluded that the project as proposed will be in compliance with the Americans with Disabilities Act and all other Federal, State and local disability rights laws and regulations and will allow the full inclusion of persons with disabilities. These requirements include, but are not limited to:
1. Having staff trained in how to provide reasonable modifications in policies, practices and procedures;
2. Having auxiliary aids and services available in a timely manner in order to ensure communication access;
3. Ensuring that any service areas and related facilities open to the public are architecturally accessible and have been inspected and approved by the DPW Access Compliance Officer or the Mayor's Office on Disability Compliance Officers.

If such access would be technically infeasible, this is described in the comments section below:

Comments:

Departmental ADA Coordinator or Mayor's Office of Disability Reviewer:

Ron Weigelt
(Name)

Director of Human Resources and Interim Director, EEO, and Cultural Competency Programs
(Title)

Date Reviewed: 10/26/15

Darlene C. Drew
(Signature Required)

Department Head or Designee Approval of Grant Information Form:

Barbara A. Garcia, MPA
(Name)
Director of Health
(Title)
Date Reviewed: 10/27/15

(Signature Required)

GILEAD INVESTIGATOR-SPONSORED RESEARCH (ISR) BUDGET FORM

Date of Submission:	4/5/2015
Study Title:	Curing HCV in Incarcerated Patients (CHIP)
Primary Investigator:	Milton Estes, MD and Alexander Chyorny, MD
Institution:	San Francisco Jail Health Services and Adult Custody Health Services Santa Clara Valley Health and Hospital System
Budget Period:	10/1/2015 - 3/31/2017

BUDGET COMPONENTS	# of Units	$ per Unit	TOTAL COST	Year 1 2015 (3 months)	Year 2 2016 (12 months)	Year 3 2017 (3 months)	COMMENTS
STARTUP							
IRB Fees[d]:							
	1	$4,500.00	$4,500.00	$4,500.00			University of California, San Francisco's (UCSF) Committee on Human Research (CHR)
	1	$2,500.00	$2,500.00	$2,500.00			Santa Clara Valley Medical Center's Research and Human Subject Review Committee
ENROLLMENT/DATABASE SETUP							
Personnel Costs[b]:							
	528	$48.15	$25,423.20	$25,423.20			Program Director (Program Coordinator III) - $48.15 Hourly (hired on Oct. 1, 2015)
	2,080	$48.15	$100,152.00		$100,152.00		Program Director (Program Coordinator III) - $48.15 Hourly
	2,080	$32.14	$66,851.20		$66,851.20		Patient Navigator I (Community Health Worker III) - $32.14 Hourly
	2,080	$32.14	$66,851.20		$66,851.20		Patient Navigator II (Community Health Worker III) - $32.14 Hourly
				$8,643.89	***$79,510.50***		***Fringe Benefits (SF Study Center) - 34%***
	104	$102.09	$10,617.36		$10,617.36		Statistician CSTI (UCSF overhead) - $102.09 - Hourly @ 10% FTE (hired Jan. 1, 2016)
	104	$103.10	$10,722.40		$10,722.40		Statistician CSTI (UCSF overhead) - $103.10 - Hourly @ 10% FTE (2% salary ↑ 7/2016)
					$7,138.15		***Fringe Benefits (UCSF) - 33.45%***
Laboratory Test Costs[e]:							
	0	$0.00	$0.00				All tests and laboratory costs will be covered under SFDPH & Santa Clara Valley Health &
	0	$0.00	$0.00				Hospital
Materials/Supplies/Shipping Costs[c]:							
	2	$250.00	$500.00				CHIP requests $250 in material costs per site for each year for the following materials:
	2	$150.00	$300.00	$300.00			printer ink (2 per package)
	2	$20.00	$40.00	$40.00			folders
	2	$30.00	$60.00	$60.00			pens, highlighters, pencils, whiteout
	2	$50.00	$100.00	$100.00			paper
Other Expensese[a]:							
UCSF CSTI expenses					$51.00	$14.00	UCSF Data & Network Recharge
					$107.00	$29.00	Computing & Communication Device Support Services
					$189.00	$13.00	General Automobile & Employment Liability self-insurance program (GAEL)
					$639.00	$173.00	Computer Services Support
POST ENROLLMENT/DATABASE ANALYSIS							
Personnel Costs[b]:							
	520	$48.15	$25,038.00			$25,038.00	Program Director (Program Coordinator III) - $48.15 Hourly
	184	$32.14	$5,913.76			$5,913.76	Patient Navigator I (Community Health Worker III) - $32.14 Hourly
	184	$32.14	$5,913.76			$5,913.76	Patient Navigator II (Community Health Worker III) - $32.14 Hourly
						$12,534.28	***Fringe Benefits (SF Study Center) - 34%***
	52	$103.10	$5,361.20			$5,361.20	Statistician CSTI (UCSF overhead) - $103.10 (Hourly @ 10% FTE)
						$1,793.32	***Fringe Benefits (UCSF) - 33.45%***
Other Expenses[a]:							
	100	$75.00	$7,500.00		$7,500.00		financial assistance for 100 participants, 50 from each site
	2	$1,250.00	$2,500.00		$2,500.00		$1,250 in traveling costs per site per year.
STUDY DATA PRESENTATION							
Travel to Scientific Conferences[g]:							
	1	$2,000.00	$2,000.00			$2,000.00	CROI 2017
	1	$2,000.00	$2,000.00			$2,000.00	AASLD 2016
STUDY DATA PUBLICATION							
Publication Costs[f]:							
	1	$750.00	$750.00			$750.00	actual costs will be determined by journal
	0	$0.00	$0.00				
Indirect Costs (if any)[h]:	*0.10*	*$470,108.34*	*$47,010.83*	***$47,010.83***			*Sponsor/Overhead charge (SF Study Center) - 10% of gross receipts (subtotal)*
					$10,017.73	$2,510.40	Sponsor/Overhead charge (UCSF) for Statistician *only* - 34% of gross (subcontract)
	1	$834.00	$834.00	$208.50	$834.00	$208.50	SF Study Center general liability (prorated for $834.00 between April 2015 - April 2016)
	4	$100.00	$400.00	$25.00	$400.00	$50.00	SF Study Center employee liability ($100/ employee x 4 employees)
Total Annual Study Budget:				$41,775.59	$364,080.54	$64,252.22	
Study Budget Subtotal:						**$470,108.34**	sponsor/overhead charge not included in subtotal

8225

Amount/Proportion Requested from Gilead:	**$517,119.17**	**SF Study Center sponsor/overhead charges <u>included</u> (10%)**
Amount/Proportion Requested/Funded by Outside Sources:	$0.00	

<u>Note:</u> If Study Drug is requested, please provide this information on the ISR Submission Form, not the ISR Budget Form.

[a]Specify type, quantity, and per-test cost, and note whether other payors (e.g., government or other health plan) will or will not cover all or any part of laboratory costs.
[b]For each personnel, specify responsibilities, qualifications, an estimate of the total number of hours to be devoted to the project and the hourly rate. Do not include annual salaries or fringe benefits.
[c]Provide a detailed breakdown for each type of material and supply item (both unit cost and quantity), and shipping costs. Equipment/supplies that can be re-used for purposes other than this study cannot be purchased.
[d]Provide an explanation of how the IRB fees were calculated and provide a copy of the institutional fee schedule if applicable.
[e]Specify and provide a detailed breakdown for each expense.
[f]Publication costs should be listed by abstract and/or slide/poster development, poster printing, manuscript development, etc.
[g]Costs for travel to scientific conferences for the purposes of data presentation from this study (if not paid by the sponsor institution) may be submitted to Gilead. These costs should be listed separately and are contingent upon abstract acceptance by that conference.
[h]Provide a detailed breakdown for any indirect costs and a copy of any institutional policies about the calculation of such costs.

ERSONNEL

Medical Director - 25% FTE – In-Kind

There will be two Medical Directors overseeing CHIP at the San Francisco and Santa Clara county jails. Their primary roles are to assist launching the HCV screening and treatment program in both jail settings, assist recruiting eligible inmates to the CHIP program and approve their Harvoni treatment, provide primary care to inmates in the jail settings, and assist supervising the CHIP staff. Both Medical Directors agree to add these responsibilities to their daily tasks without compensation.

Program Director - 100% FTE

The Program Director (Program Coordinator III) will oversee the entire CHIP program for both sites and will be responsible for launching the pilot program. Their primary roles are to create and mandate IRB protocols, manage the program budget, oversee CHIP staff, facilitate both the staff and Provider Advisory Board (PAB) meetings. The Director will also assist Navigators recruiting participants and facilitating navigation services for participants in the community. They will also develop and manage the program's database for evaluation and develop measurements for quality improvement. This position will require a graduate degree in the health field and minimum of two to three years of experience of administrative or management experience with primary responsibility for overseeing, monitoring, or coordinating a health service program.

Patient Navigators - 100% FTE

There will be two Patient Navigators who will be responsible for screening inmates in the jail setting, providing HCV results and education. They will also be responsible recruiting inmates, collecting consent forms from participants, collecting labs to monitor their treatment, and data entry. Patient Navigators will also be responsible for navigation and short-term case management services and administer Harvoni treatment to inmates released into the community during their treatment regimen. They will follow up with participants periodically to assure medication adherence, provide adherence counseling, link them to primary care, and refer them to social resources participants may need. Staff will be required to have a minimum of two to three years of experience providing health services to marginalized populations and STD, HIV, or HCV screening experience. Desired qualifications will include phlebotomist certified, and fluency in the Spanish language.

Statistician (UCSF CSTI) - 10% FTE

The part-time Statistician from University of California San Francisco (UCSF) will assist with the development of the database to monitor the CHIP program and the variable we will measure for evaluation. She will primarily assist CHIP with the evaluation for the pilot program and assist with the write up of the program. (Please see Statistician Justifications tab for justification).

Professor Hilton joined the UCSF faculty in 1990 after earning the Doctor of Science degree in biostatistics at Harvard University. Prior to her studies at Harvard, she spent 3 years at Mayo Clinic in the Department of Epidemiology and in the Comprehensive Cancer Center, using earlier training in biology and in epidemiology (MPH, Tulane University). At UCSF, Professor Hilton researches methods for exact inference, teaches clinical trial methods, and collaborates on a wide range of biomedical topics, including longitudinal epidemiologic studies of HIV, individual- and cluster-randomized trials, and mechanical properties of dentin. She has held several offices in statistical societies, including 1997 President of the Western North American Region of the International Biometric Society and Chair of the Society's Y2K International Biometric Conference.

Dr. Joan Hilton, DSc, MPH, will serve as Co-investigator on the research team, contributing broadly to the design and conduct of the research in addition to conducting statistical analyses of study outcomes. Dr. Hilton is a current Epidemiology and Biostatistics professor at UCSF. Dr. Hilton will collaborate closely with Dr. Luetkemeyer to develop and ensure integrity of data collection instruments for this multi-site longitudinal observational study, accommodating systematic differences between operations at the two jails both during and following incarceration. Dr. Hilton also will oversee development of the study database that will allow us to address the primary and secondary objectives (each with multiple parts and study outcomes, including but not limited to longitudinal SVR12; planned and completed integrated HCV testing both during the trial and historically, with refusal rate estimation; estimation of the prevalence of HCV active cases, based on the jail census, the number of inmates screened, the number of HCV antibody positive tests, and the number of active HCV RNA cases present during the study period).

**CV is avaible upon request.*

HCV Provider Consultant - 10% - In-Kind

Dr. Annie Luetkemeyer will act as Co-Investigator and CHIP's HCV medical advisor to the medical staff in both jails. Dr. Luetkemeyer will serve as a consultant to the providers upon request. She will also participate in case conference meetings and upon request by the Medical Director. She will also be an active member on the Provider Advisory Board.

Provider Advisory Board - 10% FTE – In-Kind

The Provider Advisory Board (PAB) consists of HCV providers, staff from local HCV organizations, and staff from the Department of Public Health. The PAB is the current committee designing the CHIP treatment program. Staff will continue to volunteer their time for frequent meetings to assess the program's progress, determine how to improve services, and expand community resources for the linkage to care portion of the CHIP program.

OTHER RESOURCES

Fiscal Sponsorship/Intermediary - 10% of Gross Receipts

CHIP is seeking fiscal sponsorship with the San Francisco Study center to oversee the 1-year program in both San Francisco and Santa Clara. This San Francisco-based organization has been supporting community projects, ideas, and partnerships with fiscal sponsorship and the support of shared 501(c)3 status. SF Study Center will provide back office services like; financial management, human resources, and grant management. Overhead charges will include 10% of the gross receipts and a 34% overhead charge for the UCSF Statistician's wages.

Supplies and Materials - $1,000

The majority of materials and supplies will be covered under the SFDPH & Santa Clara Valley Health & Hospital jail services. However, both sites requesting $250.00 per year for a total of $500 each project year. Materials will include costs for paper, ink, filing folders, pens and letterheads.

Financial Assistance - $25,000

CHIP will provide financial assistance of up to $75 for inmates who are willing to participate in the 12-week treatment program. CHIP expects to recruit 100 participants throughout the one year-program. Both the San Francisco and Santa Clara county jails will recruit 50 inmates for the treatment program. The $75 will include a small stipend to put on their books while in jail. It will also cover financial assistance for inmates who are released during their treatment regimen which include; taxi vouchers, food assistance, and other resources that will help participants maintain treatment.

Travel Costs - $5,000

Travel costs will include gas, parking, and bridge tolls made by the CHIP staff. This will mainly be provided to the two Site Coordinators who will be visiting the county jails and meeting with released participants who are still on their treatment regimen. Each Site Coordinator will be given $2,500 for the 2-year program.

SF Study Center's General Liability (Sponsor) - $834.00/year

The general liability premium is based on payroll of $834.00 per year, which is the annual cost from April 1, 2015 to April 1, 2016. The liability will be prorated for the last three months of 2015 and the first three months of 2017.

SF Sudy Center's Professional Liability - $100.00/staff per year

The general liability premium is based on payroll of $100.00 per year, which is the annual cost from April 1, 2015 to April 1, 2016. The liability will be prorated for the last three months of 2015 and the first three months of 2017. The $100.00 per employee would be extended to the four staff.

UCSF Data & Network Recharge - $65

UCSF has installed a high quality network for transmission of information and data at the campus level. The network directly supports numerous campus systems for support of research, training and patient care, and is widely utilized by all UCSF personnel. The costs for this network are being distributed campus-wide to all employees, and are based on effort provided for each project. For the 2015-2016 year, costs are estimated at $41 per month per employee and $44 per month per employee for the 2016-2017 year. Per review and agreement by our cognizant federal agency, UCSF data network costs are an allowable direct expense. Questions from the sponsoring agency regarding this charge should be directed to the Department of Health and Human Services -Division of Cost Allocation, San Francisco CA.

Computing and Communication Device Support Services - $135

Computing and communication device support services (CCDSS) provides integral support to campus voice and data technology functions. CCDSS includes software installation/updates, internet security, hardware setup/configuration, and centrally managed patching, storage and backup. The university charges these expenses to all funding sources based on a monthly recharge rate of $86 per FTE effective 7/1/15-6/30/16 and $92 per FTE effective 7/1/16-6/30/17, consistent with the university's current methodology used for data network services. The recharge rates are provided for under our approved DS-2, will be computed in accordance with applicable OMB requirements, including 2 CFR Part 220 (formerly Circular A-21), and will be reviewed and adjusted annually.

General Automobile & Employment Liability self-insurance program (GAEL) - $202

The UCSF mandated charge for GAEL assessment is: FY 2015-2016 @ $0.85/$100 of salaries; FY 2016-2017 @ $0.93/$100 of salaries; FY 2017-2018 @ $1.01/$100 of salaries, until amended. These expenses will be captured as a benefits expense on the financial reports.

Computer Services Support - $812

The proposed project is housed in the department of epidemiology and biostatistics. This infrastructure is considered a direct cost, and part of the expense of running a state-of-the-art research staffed primarily by statisticians and scientific researchers. The work performed there is data-intensive and requires a sophisticated computer system that performs reliably and with a high level of security. This network is specifically designed to accommodate this type of research, which is comprised of large, collaborative data collection and analysis efforts involving investigators and clinical sites around the world. Computer staff manage all aspects of this network, which falls outside the purview of the University network supported by the indirect rate. The computer network staff provide ongoing maintenance of and upgrades to the network and email services, order all computer supplies, and install hardware and software for all users. Full desktop support is provided by the computer staff at the end user level, and this support is available to all employees. At the structural level, the network staff continues to expand and upgrade the quality of cabling, servers and server software in order to maintain the high technical capacity for supporting the expanding research needs at this location.

GILEAD
Advancing Therapeutics.
Improving Lives.

October 9, 2015

Milton Estes, MD
San Francisco Department of Public Health Jail Health Services
798 Brannan Street
San Francisco, CA 94103

Dear Dr. Estes,

I'm pleased to inform you that Gilead Sciences, Inc. has approved your investigator-sponsored research proposal titled, "Curing HCV in Incarcerated Patients (CHIP)." This study (IN-US-337-1941) was approved for the provision of LDV/SOF and financial support of $517,119.17 USD. The anticipated number of subjects to be included is 100.

Timelines for this study are as follows:

- Award date: July 31, 2015
- Project start-up date (planning and preparation): October 1, 2015
- Pilot implementation date: January 1, 2016
- Pilot end date: December 31, 2016
- Project close-out date (data analysis): March 31, 2017

Congratulations on the approval. We appreciate your interest in the Gilead Hepatitis C Phase 4 program and look forward to a successful collaboration with you on this important study

Sincerely,

Lorenzo Rossaro, MD
Sr. Director, Medical Affairs
Gilead Sciences
333 Lakeside Drive
Foster City, CA 94404
(650) 358-3691 (phone)
Lorenzo.rossaro@gilead.com

cc: Annie Son, Clinical Operations, Gilead Sciences
Hadley Le, Manager, Medical Affairs, Gilead Sciences
Amanda Copans, Associate Director, Medical Affairs, Gilead Sciences

Mojica, Richelle-Lynn (DPH)

From: Yoshida, Maya (DPH)
Sent: Tuesday, October 20, 2015 3:33 PM
To: Mojica, Richelle-Lynn (DPH)
Cc: Monico Klein, Kate (DPH); Huang, Cynthia (DPH)
Subject: CHIP Payment Schedule request

Below is Gilead's proposed payment schedule for the CHIP project to add to the Accept and Expend submission. Please let me know if I need to provide the documentation below in a Word document.

Maya Yoshida-Cervantes, MPH
Project Coordinator
Curing HCV in Incarcerated Patients (CHIP)
HIV & Integrated Services
Jail Health Services, SFDPH
415-581-3122
maya.yoshida@sfdph.org

From: Annie Son (Contractor) <Annie.Son@gilead.com>
Sent: Tuesday, October 20, 2015 3:29 PM
To: Yoshida, Maya (DPH)
Subject: RE: CHIP request

Dear Maya,

Below please find a proposed payment schedule for Dr. Estes' study IN-US-337-1941. Please note that there may be some slight adjustments during negotiations and this draft is intended for the purpose described in your email below. If there is further information I can provide, please let me know and I will happily send it your way. Thank you very much!

Milestone Payment Schedule	
(i) Upon execution of this Agreement, receipt of the final Protocol, Informed Consent Form and IRB/EC approval;	**$128,279.81**
(ii) Upon notification of enrollment of 25 Study subjects;	**$83,381.87**
(iii) Upon notification of enrollment of 50 Study subjects;	**$83,381.87**
(iv) Upon notification of enrollment of 75 Study subjects;	**$83,381.87**
(v) Upon notification of enrollment of 100 Study subjects;	**$83,381.87**
(vi) Upon delivery to Gilead of (A) a copy of the abstract for interim data analysis as described in the Study publication plan and all supporting data; or (B) if the Study is earlier terminated, a summary of Study findings up to termination and all supporting data;	**$17,103.96**

(vii) Upon notification to Gilead of acceptance of an abstract for presentation and approval by Gilead of Investigator's proposed travel plan to AASLD 2016 or an equivalent conference approved by Gilead. Travel costs must be limited to reasonable travel (economy class airfare, rail), accommodations, ground transportation, and meals, in accordance with industry standards;	**$2,000.00**
(viii) Upon delivery to Gilead of (A) a copy of the abstract for final data analysis as described in the Study publication plan and all supporting data; or (B) if the Study is earlier terminated, a summary of Study findings up to termination and all supporting data;	**$17,103.96**
(ix) Upon notification to Gilead of acceptance of an abstract for presentation and approval by Gilead of Investigator's proposed travel plan to CROI 2017 or an equivalent conference approved by Gilead. Travel costs must be limited to reasonable travel (economy class airfare, rail), accommodations, ground transportation, and meals, in accordance with industry standards;	**$2,000.00**
(x) Upon delivery to Gilead of (A) a copy of the manuscript for final data analysis as described in the Study publication plan and all supporting data; or (B) if there is no acceptance of such Publication submitted, a copy of the manuscript submitted for publication and all supporting data; or (C) if the Study is earlier terminated, a summary of Study findings up to termination and all supporting data;	**$17,103.96**
Total	**$517,119.17**

Sincerely,

Annie Son, CCRP
Clinical Trial Management Associate
Gilead Sciences, Inc.
333 Lakeside Drive, Building 300
Foster City, CA 94404
650-378-2175 (office)
650-524-9531 (fax)
annie.son@gilead.com

From: Yoshida, Maya (DPH) [mailto:maya.yoshida@sfdph.org]
Sent: Tuesday, October 20, 2015 1:44 PM
To: Annie Son (Contractor)
Cc: Monico Klein, Kate (DPH); Estes, Milton (DPH); Luetkemeyer, Annie (UCSF); Chyorny, Alexander
Subject: CHIP request

Hi Annie,

We received notice from the Grants Manager at SFDPH and the City Controller's office that we need to provide documentation of the suggested payment schedule you originally provided in the draft contract. We do not need specific dates, just the attached page you included in 'Exhibit B: Budget and Payment Schedule.'

If this request is possible, please email it to me as soon as possible, so we can proceed with the submission request to the city. Please contact me if you have any questions or concerns. Thank you.

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STUDY TITLE

Curing HCV in Incarcerated Patients (CHIP)

THERAPEUTIC AREA

HCV

STUDY PRODUCT

Ledipasvir/SOF (Harvoni®)

PRIMARY INVESTIGATOR

Principal Investigator
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STUDY PROPOSAL (check all that apply)

Program Type:

- Interventional: Prospective Cohort

Scope of Trial:

- Efficacy
- Screening
- Diagnosis
- Therapy

Clinical Design:

- Pilot Study
- Non-Randomized
- Adherence

***Scientific Rationale** (0 to 1,500 maximum characters) – 1,475

The release of the recently approved fixed dose combination of sofosbuvir and ledipasvir, Harvoni, provides a unique and important public health opportunity. Incarcerated individuals have higher rates of hepatitis C (HCV) and are more likely to engage in HCV-related risk behavior compared to the general population.[1] However, that same population is less likely to be screened and treated for HCV, due to drawn out treatment time and severe adverse effects from former treatments. Medical care for HIV and tuberculosis has demonstrated that treatment in custody can break the cycle of forward transmission in highly impacted communities and reduce end-stage diseases. Treatment of HCV disease with Harvoni has been demonstrated to achieve sustained virologic response (SVR) as early as 8 to 12 weeks.

The San Francisco and Santa Clara county jails are ideal platforms to implement HCV screening and treatment paired with patient navigation services. Both settings have populations highly impacted by HCV with minimal access to HCV treatment and limited utilization of linkage to local health services. Jail settings can provide an optimal opportunity to screen for HCV, initiate curative treatment, and link patients to community HCV providers. Intensive patient navigation, leveraged with a strong community network, would be an essential component for treatment to ensure adherence and achieve SVR for those who are discharged from jail prior to HCV treatment completion.

Background

Background: The CDC recommends a one-time HCV screening for those who have ever been incarcerated. Unfortunately, implementation of jail-based HCV screening is lacking in many US jails and prisons, which misses a critical opportunity to identify and ultimately treat a highly impacted population. Currently, it is estimated that more than 3.5 million Americans are infected with HCV, where 65-75% of them are either unaware of their status or not receiving care.[2] Untreated chronic HCV can lead to cirrhosis, liver cancer, end stage liver disease, as well as non-hepatic complications. The number of deaths attributed to HCV steadily rose from 4,839 to 6,572 between 2002 and 2007.[3] Given the remarkable recent advances in HCV treatment, nearly all patients with chronic HCV now have safe, well-tolerated oral treatment options that are highly effective in curing HCV. Therefore, it is critical to screen high-risk patients, provide education to reduce transmission, and link HCV+ patients to medical care in order to reduce HCV-related morbidity and mortality and break the cycle of ongoing transmission.

The Centers for Disease Control and Prevention (CDC) estimates that 75% of all chronic HCV carriers in the United were born between 1945 and 1965, and recommends a one-time HCV screening, regardless of risk.[4] In addition, the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (ISDA) recommend for individuals to be screened for HCV if they report any injection or intranasal illicit drug use, received tattoos from an unregulated setting, have ever been incarcerated, or are HIV positive.[5]

* Mandatory items from the Gilead application

The HCV burden is even higher among marginalized populations, including incarcerated individuals, due to the high rates of illicit drug use and engagement in high-risk behaviors.[6]

HCV Prevalence and Missed Opportunities in the Incarcerated Population: The United States has one of the highest incarceration rates in the world where approximately ten million people were placed in local, state, or federal correctional facilities—a 500% increase over the last thirty-five years.[7] As of 2013, over 2.2 million people were imprisoned and another five million were under the control of the corrections system either on parole or probation [7,8]. There have been a number of attempts to quantify the HCV burden among incarcerated populations in the United States. A total of 11 cross-sectional studies that date from 1987 and to 2013, estimated the HCV prevalence in the prison systems anywhere from 10.1% to 41.2%, which is at least seven times greater than that of the general population. [1,9-20] In the *"Chronic Hepatitis B and Hepatitis C Infections in California: Cases Newly Reported through 2011,"* 16% of all newly reported chronic HCV cases in California in 2011 originated from the state prisons.[21]

While prevalence rates from prisons may provide an insight to what might be expected in jails, the two populations are inherently different.[9] Jails are locally operated, short-term facilities that have a higher turnover rate due to a wide spectrum of people who are awaiting arraignment, trial, conviction, sentencing, or serving short sentences.[9] Studies investigating HCV in the jail systems report a prevalence rate that ranges from 13% to 31.1%; however, the true prevalence rate in the California jails remain unknown due to minimal utilization of HCV screenings.[9,22,23] Approximately 9 million detainees pass through jails each year compared to an annual 1.5 million inmates in the prison system.[1] Of those released from jail, approximately 67.8% recidivate within three years of their release.[8] The majority of persons entering and reentering jails represent the most marginalized populations where they are disproportionately people of color, lower socioeconomic status, lower educational attainment, uninsured, unemployed, and homeless.

In 2011, California enforced the Public Safety Realignment Act to reduce the overcrowding of state prisons, high costs, and high recidivism rates. As a result, there was a significant shift that redirected non-serious, non-violent, and non-sex registrant offenders from state custody to the local jurisdictions. [24] As a result, California jails were projected to grow by about 8,600 inmates between June of 2011 and 2012 while the State prison population declined by 26,600.[24] These changes lengthened the overall length of stay in jails, representing a pivotal public health opportunity to initiate HCV screening and treatment for this high-risk, transient population before they are released into the community. For many uninsured inmates, this may be the only stable access to medical care, particularly among the younger population who are experiencing increased prevalence rates, yet are often underdiagnosed.[10]

HCV Treatment Cascade and the Incarcerated Population: The HCV Treatment Cascade serves as a reminder of the existing HCV care delivery gaps in the United States, including those in the incarcerated systems. Significant improvements are needed in every step of the cascade in order to improve the overall percentage of achieving SVR (Figure 1). The diagnosis and treatment segment of the cascade continue to play a critical role in the framework. When comparing HCV treatment cascade with that of HIV care continuum, HCV care falls markedly behind, particularly with diagnosis and treatment.[25] Among the reported 3.5 million living with

chronic HCV, 16% were prescribed HCV treatment, and only 9% achieved SVR. According to the cascade, only 50% of HCV positive people are aware of their status and of those, only 43% have access to outpatient care.[26] While the authors of the 2014 HCV Treatment Cascade acknowledged the lack of representative data from the incarcerated and homeless population in this summary, it is assumed that the cascade would be more severe. The gap between the total number infected and the proportion of diagnosed is likely to be wider given the lack of uniform adaptation of screening protocols in jail systems. Since the current practice guidelines for the incarcerated population also specifies prioritization of treatment for inmates with cirrhosis, the number of those who successfully initiated therapy is further limited.

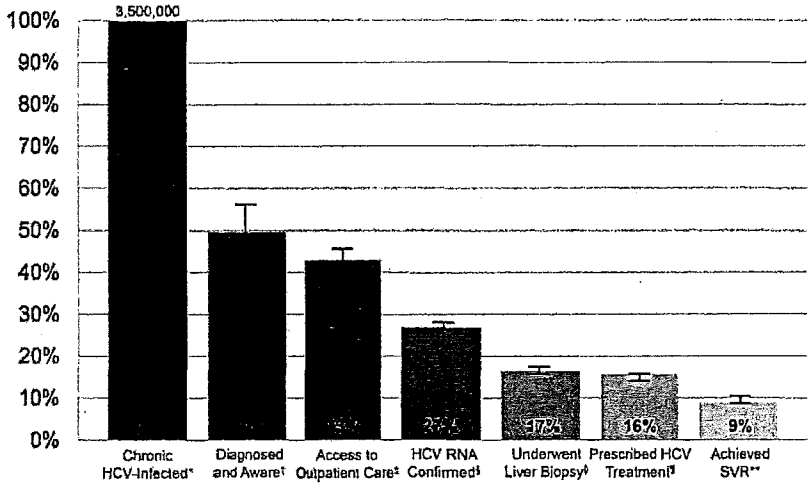

Figure 1. HCV Treatment Cascade

While the screening and expansion of treatment can be improved with policy changes to increase access, linkage and engagement in care will require an integration of patient navigation services for marginalized populations. The time following release from incarceration is a particularly vulnerable period for former inmates with chronic health problems. [27] Healthcare utilization is often low, most lack health coverage, and are provided with an insufficient supply of chronic medications upon release.[27 28] Approximately 90% of those released from jail are currently uninsured and lack financial resources to access comprehensive medical care, where 80% have some sort of chronic medical, psychiatric, or substance abuse problems.[29 28] The success of linking patients to medical services and ensuring medication adherence through navigation and support services are demonstrated in transitional HIV care model for the incarcerated population and can be adapted for HCV. [30,31]

Proper navigation assistance to link released inmates to medical care and social services is a critical component to improving the HCV treatment cascade rates and reducing the persistent healthcare disparities. The best documented models for promoting reintegration and improving healthcare utilization involve short-term, comprehensive case management services paired with discharge planning. The San Francisco County Jail reported that inmates who received discharge planning prior to their release were more likely to maintain a regular source of care in the community.[28] Several models have demonstrated success of intensive short-term patient navigation to linking patients to care during the vulnerable time immediately after incarceration. New York State currently has a Hepatitis C Continuity Program to promote treatment completion upon and after release to the community.[32] Inmates receiving treatment prior to their release are provided with timely referrals to local community-based healthcare providers for continuation of their treatment. Prior to release, linkage specialists consult with

* Mandatory items from the Gilead application

the inmates to enroll them in health coverage and determine which provider they will be referred to. Parole Officers are additional resources who provide access to supportive services for released inmates on treatment.[32]

In Rhode Island, Participants of the Community Partnership and Supportive Services for HIV-infected People Leaving Jail (COMPASS) provided six-month case management services to released jail detainees.[31] Community health workers met with inmates during intake to assess their needs so they could immediately be linked to the various medical and social services upon their release such as HIV primary care, substance abuse treatment, mental health services, housing, employment programs, food assistance, and legal aid. [31] Similar to COMPASS, the San Francisco's Department of Public Health opened a Transitions Clinic (TC) at a community health center that provided primary care and peer case management services for prisoners returning to San Francisco.[29] The TC program, in particular, was most effective in smaller geographic settings, because the case managers heavily relied on its local resources.[31] Importantly, a recent cost-benefit analysis reported that treating HCV positive inmates in jails can be beneficial if there are appropriate links to community services to maintain continuity of care at discharge. [11]

Evolution of HCV Treatment Recommendations & Limited Access in the Incarcerated System: The introduction of Hepatitis C Direct Acting Agents (DAA's) has significantly altered the treatment paradigm. In addition to improving SVR rates, treatment duration has also been shortened. In the 2014 update, the California Correctional Health Care Services' (CCHCS) Care Guide for Hepatitis C and the Federal Bureau of Prisons Clinical Practice Guidelines included sofosbuvir and simeprevir based regimens as the current HCV standard of care. These updates reflect the correctional systems attempts to mirror HCV treatment trends in the community. The treatment selection process also resembles some of the processes adapted by various managed care and commercial plans such as liver disease staging. As recommended in the CCHCS guidelines, the "Release Date Exclusion" criterion for inmates released in less than five months for all genotypes essentially means that treatment continues to be deferred until they are transferred to a mainline institution.[33]

In a recent cost analysis on the treatment of chronic genotype 1 HCV infection among the incarcerated population, a sofosbuvir-based regimen was projected to produce the greatest overall benefits in reduction of decompensated cirrhosis and hepatocellular carcinoma along with a gain of 2.1 quality-adjusted life-years, at a cost of $54,000 compared to no treatment.[34] This cost benefit was more pronounced for the group with a shorter sentence. The upfront costs for treating 500,000 incarcerated persons was approximately $32 billion; however, this cost was offset by the $2 to $5 billion in savings to public entities such as Medicaid after their release.[34] This study also factored in reinfection risks in its analysis. The findings of this modeling analysis not only demonstrated cost saving benefits to the system as a whole, but also individual health outcomes. It is therefore crucial to expand HCV treatment in all correctional settings, particularly those cycling through the jails as they mirror the population in this analysis.

Access to treatment for all HCV infected inmates: The current IDSA/AASLD guidelines advocate treatment of all HCV-infected persons, based on the large body of evidence showing benefit of curative therapy regardless of the stage of liver disease. The availability of the DAAs

has finally put widespread HCV treatment within reach. Universal treatment for those without a contraindication will not only reduce the morbidity and mortality rates, but may also turn the tide on the HCV epidemic by reducing ongoing transmission, as has been demonstrated in several models of scaled up access to HCV treatment. The public health may particularly benefit by addressing HCV in the incarcerated settings where there is a larger population of individuals who engage in higher risk behaviors such as PWID, tattooing, and sexual contact.[35] In addition, for many incarcerated patients, time in jail represents the best opportunity for stable contact with a medical provider and therefore successful initiation of HCV treatment.

DAA's For Treatment in Jail Setting: The recently approved of sofosbuvir (SOF) and ledipasvir (LDV) fixed dose combination, Harvoni, for Genotype 1 HCV has many characteristics that make it an optimal candidate to address the HCV treatment barriers in jails. Treatment duration can be as short as eight weeks for treatment naïve patients with HCV RNA level below 6 million IU/mL without cirrhosis.[36] It does not require the use of ribavirin and interferon that add to the toxicity of HCV treatment and limits treatment eligibility. If inmates need to complete their treatment in the community, the co-formulated once daily regimen may provide additional benefits for adherence and medication access. Harvoni is ideal for a high volume public health based HCV treatment approach in the jail setting due to excellent tolerability, limited drug interactions, and minimal drug contraindications. Importantly, Harvoni can be used in HIV-HCV coinfection; SVR12 rates in this population are high and Harvoni is compatible with most antiretroviral regimens.[40] Despite these promising characteristics, the feasibility of using oral DAA regimens for widespread therapy in the jail setting has not been evaluated. Furthermore, the structural supports needed to provide high volume HCV treatment to jail inmates have not yet been fully explored.

San Francisco and Santa Clara Jails: The San Francisco (SF) and Santa Clara (SC) Jails are urban settings both located in Northern California. Approximately 1,200 inmates reside in the SF and 3,700 reside in the SC jail, respectively. The average length of stay for inmates in the SF jails ranges from 72 hours to four months, with over half of inmates with a length of stay of 3 months or more. The average length of stay for inmates in SC jails is about six months, not including inmates who are cited and released. This substantial length of stay represents an opportunity for initiation and closely monitoring of HCV treatment for many inmates. True estimates of HCV prevalence are not available from either jail site. From the literature, antibody prevalence in jails has ranges from 13-20.5%.[9 10]

Current testing strategies: In SC, Adult Custody Health Services performed 771 antibody tests as part of routine medical care when there is a clinical indication, provider-offered risk-based screening, or per inmate request. Of those tested, 135, or 17.5% were positive (up to 21% if weakly positive tests were included). However, universal opt-out or integrated testing is not currently offered in SC jails. A pilot testing project is underway at the two SC jails based on an integrated HIV and HCV screening method to expand HCV testing. The SF Jail Health Services' (JHS) HIV and Integrated Services (HIV-IS) provides HCV antibody testing as part of their routine integrated screening method during intake and at jail housing unit orientation, which also includes HIV and STD testing. In 2014, HIV-IS provided 1,354 antibody tests, where 11% were

* Mandatory items from the Gilead application

HCV antibody positive, identifying over 130 HCV cases of which 51 were not previously identified. Current protocols do not collect the number of inmates who decline testing.

Current HCV Treatment: To date SF and SC jails treated less than five chronic HCV inmates combined. Only one patient is currently undergoing a simeprevir-based treatment in the SC jail.

*Objectives

***Primary Objective** (0-800 characters) – 682

The primary objective is to implement a feasible HCV treatment program in two urban jail settings, San Francisco and Santa Clara, over a **12 month period**, with demonstration of a SVR12 of 70% or greater among inmates who initiate HCV treatment by: (1) instituting HCV screening and preventative services for inmates in the urban jail settings, (2) treating identified inmates with chronic HCV, and (3) providing short-term, intense navigation services that integrates local HCV providers, community-based supportive services, and the criminal justice agencies to ensure continuity of care, medication adherence and achievement of SVR12 status for inmates released into the community.

***Secondary Objectives** (0-800 characters) - 780

1. To evaluate the efficacy of intensive, short -term patient navigation by assessing HCV adherence and the proportion of participants attaining SVR12 who were released from jail prior to treatment completion or SVR12.
2. To evaluate the impact of integrated HCV testing and increase the total number of HCV screenings over 12 months.
3. To evaluate the safety and tolerability of HCV treatment initiated in jail by assessing the proportion of patients discontinuing HCV treatment due to adverse events or intolerance.

Primary Endpoint (0-800 characters) – 149

The primary endpoint is the number and proportion of inmates attaining SVR12 after HCV treatment initiation during the 12 month CHIP program.

Secondary Endpoints (0-800 characters) – 789

1. Overall proportion of participants completing full course of therapy after initiation of HCV treatment, the proportion of inmates discharged prior to HCV treatment completion that successfully completes their prescribed HCV treatment course in the community, and the proportion of inmates treated for whom SVR12 results are ascertained.
2. Absolute number and proportion of inmates tested for HCV after implementation of augmented HCV testing program, and the number of individuals with active HCV (RNA detected) identified with augmented HCV screening at each jail site.

* Mandatory items from the Gilead application

3. Proportion of inmates who discontinue HCV treatment due to a) adverse event b) intolerance of HCV treatment, c) treatment interruption for other reasons or d) lost to follow up prior to documented completion of treatment.

*Projected Study Design

Design

CHIP proposes to implement a program modeled on evidence-based HIV and STI prevention and control services. These models highlight the importance of promoting early diagnosis and ensure persons are linked to appropriate prevention, care, and treatment services. The development of the CHIP demonstration project is guided by a combination of elements from the evidence-based HIV prevention efforts made by local organizations and health departments. In accordance with the *2014-2016 Viral Hepatitis Action Plan* and goals of *Healthy People 2020*, CHIP will institute HCV testing, care, and treatment in the jail setting to reduce health disparities, transmission risk, and liver disease. Due to the unique HCV services CHIP will provide in the jail setting, a one year demonstration project will be implemented to determine the feasibility and efficacy of the multi-prong intervention. . This pilot will be used as a leverage to prove feasibility to implement into a sustainable program.

CHIP Program: Testing, Treatment and Post-Discharge Linkage: To achieve the program's three specific aims, CHIP developed a three component program that focuses on implementing HCV screening and treating eligible inmates with Harvoni in the jail settings. The first two components will reflect the HIV "test and treatment" model to reduce adverse health consequences in the community. CHIP will implement a protocol that is consistent with the *National Strategy for Prevention and Control of Hepatitis B and C.* This service will mirror the San Francisco Jail Health Service's HIV Prevention Program (HIV-IS), where inmates are screened for integrated HIV, STD, hepatitis testing. The third component consists of intense patient navigation services for inmates released into the community before their treatment completion as a means of establishing care in the community and maintaining drug adherence. Navigation will also be provided to patients to ascertain SVR12 status. Similar to the New York State Hepatitis C Continuity Program, COMPASS, the San Francisco Department of Public Health's (SFDPH) Linkage, Navigation, and Comprehensive Services (LINCS) program, and SFPDH's Transition Clinic, CHIP promotes treatment and continuity of care upon and after release into the community. This component emphasizes the importance of establishing a short-term case management approach to assist participants to address any barriers that might affect their medication adherence. Patient navigation services will be based on the client-centered model, harm reduction model, motivational interviewing, and general social work principles to facilitate a proactive, comprehensive care plan when addressing clients' multiple medical and social needs. Services will be provided to inmates prior to their release, upon their release, and throughout their treatment course to maximize their success of medication adherence. In collaboration with local health centers that actively treat HCV positive patients, CHIP will connect their released participants to the facility of their choice for healthcare continuum and lab follow up.

* Mandatory items from the Gilead application

***Number of Subjects**

CHIP will recruit a total of 100 inmates diagnosed with chronic HCV to treat with Harvoni in the San Francisco and Santa Clara jails. Fifty inmates will be the sample size per site, as 5-10 new HCV initiations/month is a feasible number to treat at each site, given proposed staffing and infrastructure. With a goal SVR12 of 70% or greater, using an intention to treat analysis (SVR12 missing=failure), 100 patients will be able to detect at 70% SVR with a 95% CI of 60.4% - 78.1%.

*** Eligibility Criteria (Inclusion/Exclusion)**

Screening. The screening component of the program will enroll all inmates who opt to screen for HCV for the duration of the initiative. HCV testing will be offered to inmates during the medical screenings at jail intake. Outreach will also be conducted in the housing units. Any inmates who later decide to have a HCV screening can complete a Medical Care Request (MCR). Data for new HCV diagnoses from the preceding 12 months will available from each site as a comparator. Treatment will be immediately discussed and offered to inmates who are already known to have chronic HCV and who meet the other CHP criteria for treatment.

Treatment. The treatment component will be offered to all HCV infected inmates meeting the initiative inclusion criteria. To be eligible, inmates must have genotype 1 HCV and have no medical contraindications to treatment, including limited life expectancy of less than 12-months due to non-liver related comorbid conditions or renal failure with creatinine clearance of < 30 mL/min. Eligible participants must complete all the required labs and be anticipated to complete at least half of the recommended course of treatment while detained in the jail setting. For example, cirrhotic participants requiring 24 weeks of Harvoni, due to prior treatment failure, will be required to have at least 12 weeks of anticipated incarceration at the time of treatment initiations. HIV CO-INFECTION will not be excluded so long as other exclusion criteria have not been met.

Navigation. There are no sampling strategy or exclusion criteria for the navigation component of the program. All participants will receive intensive navigation services if they are released into the community during their treatment regimen. In addition, the patient navigator will provide navigation to facilitate linkage to care and documentation of SVR12 in all released inmates.

***Study Sites**

CHIP has two participating project sites, the San Francisco county jail and the Santa Clara county jail. The San Francisco jail consists of four facilities receiving medical care from the SFDPH's Jail Health Services (JHS). The Santa Clara jail consists of two facilities, Elmwood Facilities and the Main Jail, which both receive medical services from the Santa Clara Valley Medical Center (SCVMC).

Participating Countries

United States of America

***Time frame/Study duration**

* Mandatory items from the Gilead application

IRB approval and hiring of staff: October 1, 2015- December 31, 2015
One year Treatment Initiative: January 2016 – January 2017
First patient visit: January 2016
Last patient completes treatment: January 2017
Patient follow-up completed: By March 2017
- Last Patient Visit Day: January 2017

Analysis and dissemination of findings: January 2017 – March 2017

MANDATORY ENTRY FOR APPLICATION:
Estimated First Patient First Visit Date: January 1, 2016
Estimated Last Patient Last Visit Date: December 31, 2016
Projected Duration of Enrollment: 12 months (January 2016 – January 2017)
Projected Duration of Treatment: 12 months (January 2016 – January 2017)
Study Duration: 1 year

***Study Duration** (refer to Appendix A: Gantt Chart)

The entire program will require 1.5 years—one year of active intervention in addition to three months of protocol development, IRB preparation, hiring staff, and an additional three months for data analyses and presentation after enrollment has been completed. Once the program is approved by the two IRBs, staff will be hired, trained, and receive appropriate clearance to work in the jails. By January 1, 2016, CHIP will implement the 12-month pilot program. Inmates will be initiated on program provided therapy through January 1, 2017. Treatment and intense patient navigation services will be provided until the last participant completes their regimen, by January 2017, with remaining follow-up completed by end of March 2017. Participant requiring 24 weeks of treatment (treatment experienced, cirrhotics) are anticipated to be uncommon, and treatment initiation will be handled on a case-by-case basis during the last three month of the intervention period. HCV screening efforts will continue throughout the program until December 31, 2016. After January 2017, screening efforts will be transitioned to the jails' screening resources. Evaluations will be assessed throughout the program and will be analyzed by the study statistician in the last three months of the program. CHIP staff will analyze preliminary data throughout the project, with final analyses during January 2017- March 2017. The Program Director and investigators will actively address mechanisms to expand services and sustain the program at both facilities throughout the program to allow for continuation of jail based screening and treatment at the conclusion of the study.

***Regimen**
Product: Harvoni (ledipasvir and sofosbuvir)
Dose: fixed-dose combination one tablet (90 mg ledipasvir and 400 mg of sofosbuvir)
Frequency: one oral tablet per day (QD, PO)
Recommended Treatment Duration (per Harvoni package insert):
- For treatment naïve with HCV RNA < 6 million: 8 weeks
- For treatment-naïve with HCV RNA ≥ 6 million and/or cirrhosis: 12 weeks
- For treatment-experienced without cirrhosis: 12 weeks

* Mandatory items from the Gilead application

- For treatment-experienced with cirrhosis: 24 weeks

Data Collection Plan

Data will primarily be collected through the Jail Health Services' (JHS) and Adult Custody Health Services (ACHS) electronic medical records to review patients' labs and provider notes. Viral loads will be collected from participants every four weeks to measure for SVR. Labs will also be collected from the local outpatient primary care clinics to measure SVR for participants released into the community. Staff will also work with criminal justice agencies to determine participant release dates. Standard forms and databases will be developed before the implementation period begins.

Study Procedure/Frequency Table

Planning and Preparation: CHIP will have three months for IRB preparation, protocol development, and hiring staff. While the program is under review by the two IRBs in San Francisco and Santa Clara, staff will be hired, trained, and given jail clearance. Hiring and human resources will be through the program's fiscal sponsor, the San Francisco Study Center. All program protocols and materials will be finalized prior to the launch of the project.

Pilot Implementation: By January 1, 2016, CHIP will launch the one-year pilot program.

HCV Screening: The first component of the program will identify infected persons through onsite screenings. This screening component of the program will provide an improved estimated prevalence of HCV-positive inmates and identify candidates for treatment. This is of particular importance in the Santa Clara Jail where HCV screening is not routinely offered to all inmates. CHIP staff will incorporate a HCV self-report disclosure during the mandatory jail intake. All inmates with unknown or previously negative HCV antibody statuses will be offered HCV testing at intake and in jail housing units during orientation. Outreach efforts will also be made through educational workshops in the housing units to increase awareness of HCV prevention. Inmates can also request testing any time during their incarceration, either with the CHIP team or by completing a medical care request (MCR). San Francisco jails will incorporate this HCV screening process into the HIV Prevention Program.

CHIP or JHS staff will screen inmates using a serological HCV antibody test (anti-HCV). CHIP staff will be trained to test, disclose, and educate inmates about HCV. They will also offer local resources and referrals to inmates regardless of status. HCV Ab+ results will reflex to an HCV RNA test to confirm viremia. Inmates with a past history of HCV Ab+ and an unknown HCV RNA status will also be offered RNA testing. Inmates that have a viral load will then be offered a genotype test to determine eligibility. At point of disclosure of HCV viremia, staff will meet with inmates and counsel them about HCV using the harm reduction model. Inmates will also be educated on the various treatment options and either referred to community clinics or be recruited for jail-based treatment if eligible. Educational materials will be available in housing units, during workshops, and when receiving health services. Current resources are in place for

* Mandatory items from the Gilead application

jail medical staff to provide further assessment including screening for cirrhosis using labs and imaging.

Harvoni Treatment: Genotype 1 HCV viremic patients will be offered jail-based HCV treatment according to a medical provider's assessment and who meet the inclusion criteria. Inmates receiving treatment in the jail settings will follow the jail health protocols where RNs dispense Harvoni as daily directly observed therapy (DOT) until they complete their treatment regimen. Length of treatment will be determined by Gilead's recommended prescribing guidelines, encompassing the presence and absence of cirrhosis, baseline HCV RNA, and prior treatment experience.

Inclusion criteria require an anticipated incarceration of at least half the length of HCV treatment; thus, there will be inmates who are released prior to completion of HCV therapy. HCV treatment will continue post-release under close Navigator supervision. All participants will be followed for SVR12 after therapy completion, whether incarcerated or post-release at the time of the SVR12 assessment. Data will also capture treatment related adverse events leading to treatment interruption or hospitalization, treatment completion, failure to complete treatment, the reason for this failure, and patients lost to follow up (LTFU).

Intense Patient Navigation: Inmates released into the community before completion of the Harvoni regimen, will receive intense patient navigation services. Each released inmate still on active treatment will be assigned a navigator who will assist with ongoing medication adherence. The CHIP navigators will be trained to provide case management support, medical and social service navigation, and chronic disease self-management support. Case management support involves referrals to housing, employment, education, financial assistance, transportation, and legal aid. Medical service navigations facilitates access to medical care, which includes enrolling for health coverage, establishing care at a local health center that currently treats HCV positive patients, and accompanying participants to their appointments. Social service navigation includes linking participants to substance abuse counseling, mental health services, and food assistance programs. Chronic disease self-management support includes home visits for assessment and health education and medication adherence support. To ensure effective navigation services, local health departments, clinics, and organizations will be notified of the CHIP program and staff. Primary contact information from various local services will be collected before program implementation and will be revised during the pilot.

Prior a participant's release, CHIP navigators will meet with them to assess their needs, complete an intake form, and begin establishing services based on their individual needs. Navigators will collect participants' contact information and establish a plan to meet with them upon their release. Contact information will be thorough including phone numbers, addresses, family or friend's contact information, emergency contacts, and main places they hang out. Navigators will routinely meet with CHIP team for case conferences to determine best approaches and advise the next steps for each client. Routine team meetings will also include time for staff support and provide a space for staff to process their experiences. At point of release, navigators will meet with participants, provide them with a one to two day supply of Harvoni and assist them with case management services for their reentry. Services will be

* Mandatory items from the Gilead application

determined on a client-based harm reduction approach. Navigators will stay in frequent contact with participants to ensure medication adherence and ascertainment of SVR12 for inmates post discharge. Both site navigators will distribute Harvoni weekly to released participants. During their weekly visits, navigators will assess each participant's adherence and apply harm reduction methods to ensure their treatment success. Methods can include daily reminder calls, distributing medications every day, and addressing any medical or social barriers the participant may encounter.

Navigation services will be provided to each released participant until their treatment completion. Navigators will work with participants to link them to long-term case managers at a local organization, health department, or medical facility. Post treatment completion, CHIP staff will remain in contact with the participants to maintain current contact information and remind them of their lab appointments to assess for SVR12. All navigators will be responsible to document every participant encounter for data analysis and to determine a proper course of treatment via an accessible network for the site teams. Participants lost to contact will be followed up with CHIP staff using the contact information list collected during initial encounters. If participant is still lost, staff will notify their provider or case manager to send an alert in their medical record. Staff will also follow up with jails records for possible recidivism and shelter listings provided by the city's search system such as San Francisco's Coordinated Care Management System (CCMS).

End of Program: Evaluations will be assessed throughout the program and will be analyzed by a statistician in the last three months of the program. Quarterly reports will be provided to the PAB and Gilead at their request. CHIP staff will begin preliminary analyses of the program's outcomes in October 2016 with final analysis during January-March 2017 . The Program Director will also determine ways to expand services and sustain the program at both facilities with the assistance of the departments of public health and the sheriffs' departments.

IRB Statement & Consent Procedures

CHIP staff will need to apply to different Institutional Review Boards (IRB) for each project site. The San Francisco project site will apply to the University of California, San Francisco Committee on Human Research (CHR) and the Santa Clara project site will apply to the Santa Clara Valley Medical Center's Research and Human Subjects Review Committee. Access to the jails, program protocols, materials, and inmates' medical records and jail release information will be approved by the two IRBs. A consent form will be presented to the eligible inmates prior to starting Harvoni. Each potential participant will be informed of the purpose of the study, their time commitment to their participation, their financial assistance, and the possible risks and benefits of their participation. Patient information will be identified by a digit code for data entry and will not include patient identifying information. All data will be stored in locked files, password protected computers, and secure offices.

Other Evaluations

* Mandatory items from the Gilead application

CHIP will develop and track outcomes prior to the implementation of the pilot and the one-year program. Outcomes will include screening, management, treatment and SVR. Data will be compiled in an Access database that will track the participants' labs, release date, and medication adherence. For the one-year pilot program, data will be extracted and compiled on a monthly basis to review during the PAB meetings. The effectiveness of the screening component of the program will be measured by the prevalence rates that emerge from the jail population and the increased number of patients screened and treated for HCV in the county jails. Results from the risk assessment questionnaire will also be analyzed with the anti-HCV outcomes to determine an efficient method for screening in the jail settings.

Treatment and navigation services will be measured by the routine viral load tests collected for each participant at approximately every four weeks. Viral load measures will also act as a monitor to assess participant adherence. To evaluate the efficacy of the navigation services, viral loads will be analyzed. In addition, staff will analyze the site coordinator's reports about the participants, their blister pack tracking, and feedback from the participants themselves.

Quality improvement measurements will be employed throughout the pilot and program using a mixed method approach, to assess whether the three main services were implemented efficiently. QI measures will also be implemented to assess whether protocols outside of CHIP can be improved, such as assessing whether the process of lab results can be accelerated to accommodate soon to be released patients. Evaluations will assess the effectiveness of the integrated screening methods for HCV in the jail settings and the best way to identify the patient population most likely to benefit from the HCV treatment.

Statistical Methods

CHIP will analyze data collected from the Access database using SAS software. All personally identified information will be stored on a secure server and will be HIPAA compliant.

Evaluation of Primary objective:

The primary objective is attainment of SVR12 of 70% or greater in inmates initiating HCV treatment in two urban jail settings over a 12-month time period. Current SVR12 rates for genotype 1 patients receiving Harvoni in clinical trial settings are 94-100%, including those with compensated cirrhosis and with prior treatment failures.[37 38 39] In " real world" settings, observation studies such as HCV Target and TRIO have demonstrated SVR12 rates comparable to those observed in clinical trials. Assuming a 90% - 95% SVR12 in those who take all medications under DOT setting, a maximum 10% treatment discontinuation rate due to adverse events or

Across site N	Estimated SVR12	95% CI*	
100	50.0	40.4	59.6
	55.0	45.2	64.4
	60.0	50.2	69.1
	65.0	55.2	73.6
	70.0	60.4	78.1
	75.0	65.6	82.5
	80.0	71.0	86.7
	90.0	76.6	90.8
	95.0	82.4	94.6

*** Agresti-Coull method**

* Mandatory items from the Gilead application

intolerance and maximum 10% loss to follow up rate, in which no SVR12 is ascertained, we anticipate a 70-75% SVR12 if we conservatively treat missing SVR12 values as failures in the primary analysis. All participants receiving at least one dose of HCV treatment through the study will be included in the analysis. The primary analysis will exclude participants enrolled during the pilot. With a population of 100 individuals treated across both sites, the estimated 95% CI for an SVR12 rate of 70%, the 95% CI will be 60.4% - 78.1%, and for an SVR12 of 75%, the 95% CI will be 65.6% - 82.5%. We will compare SVR12 rates in those completing therapy while incarcerated to those discharged prior to treatment completion.

A logistic regression model that analyzes longitudinal HCV viral load status, based on monthly assessments from establishment of eligibility through 12 weeks after last Harvoni treatment, will be used to estimate the **SVR12 rate** as a function of jail site, proportion of prescribed days completed by DOT, and their interaction. In addition, two sensitivity analyses will be performed: (1) the logistic model will be re-fit excluding missing SVR12 values, and (2) if Secondary Objective 5 (see below) identifies covariates that explain missing SVR12 values, these covariates will be added to the model. A sensitivity analysis will be performed where the logistic model will be re-fit excluding missing SVR12 values.

Evaluation of Secondary Objectives:

1) To evaluate the **efficacy of intensive, short term patient navigation** after discharge by assessing HCV treatment completion, SVR12 ascertainment, and proportion attaining SVR12 in participants who are released from jail prior to SVR12.
2) To evaluate the impact of augmented integrated HCV testing on the **total number of HCV tests conducted** over 12-months, in comparison to current testing strategies at each site. San Francisco's JHS conducts approximately 1200- 1300 tests per year as part of their integrated screening of HIV, STDs, and HCV; the **refusal rate** is not known. Santa Clara conducts HCV testing during routine medical services when there is a clinical indication and per patient request, at a rate of about 700-800 tests per year. At the San Francisco site, refusal rates will be recorded. Total number of HCV Antibody tests completed during the intervention period with augmented patient and inmate education around HCV awareness will be compared to total tests completed during routine integrated testing in preceding years, as a **historical comparator**. In Santa Clara, evaluations will be descriptive, reporting the total number of tests conducted under implementation of new integrated testing.
3) To evaluate the **safety and tolerability** of HCV treatment initiated during incarceration. Participants discontinuing HCV treatment will be have their reason for treatment discontinuation indicated in the following dispositions; a) adverse event, b) treatment intolerance, c) lost to follow-up prior to treatment completion, and d) other reason. Based on the opinion of the treating provider, staff will indicate the type of adverse event, its severity, and whether adverse events were judged to be treatment associated or not. Throughout the treatment and follow-up periods, safety and tolerability data will be summarized by the number of inmates affected and the number of episodes per week. Since data may be more complete during incarceration, these results will be summarized both overall and by discharge status (pre- vs. post-discharge).

* Mandatory items from the Gilead application

Additional research questions will be addressed as resources allow:

4) To evaluate the impact of integrated HCV testing to identify active HCV cases (HCV RNA detectable) identified at each site over the 12 month study period. The following will be reported for each jail: the jail census, the number of inmates screened, the number of HCV antibody positive tests, and the number of active HCV RNA cases present during the study period. We also will report the screening rate, the proportion of active HCV cases out of total HCV antibody positive tests, and the **prevalence of active HCV** in the jail population during the 12-month study period.
5) To evaluate missing outcome status to address whether specific characteristics explain missing values. We anticipate that 25%-35% of study participants will be discharged during the intervention period, prior to treatment completion, and that some may be lost to follow-up after discharge in spite of tracking of discharged inmates by both probation officers and Patient Navigators. Based on the primary analysis, if the SVR12 rate is <90% at either jail and >10% of 12-weeks post-treatment HCV RNA values are missing, we will model **missing outcome status** as a function of baseline characteristics of study participants to determine if values are missing at random or if specific characteristics explain missing values.
6) As measures of **treatment adherence**, total HCV treatment days will be defined as the sum of DOT days completed (i.e., incarcerated period) plus the number of self-medication days completed according to self-report (i.e., post-incarceration). We will use Poisson regression to compare treatment adherence (i.e., the proportions of days treated) by period in order to evaluate the efficacy of Patient Navigator efforts.

Conference/Publication Plans

Program updates and outcomes will be presented to the local HCV organizations such as the HCV Task Force, the local health departments, and the Sheriff's Department. CHIP plans to submit an abstract to the annual Conference on Retrovirus and Opportunistic Infections (CROI) for 2017 and present with the American Association for the Study of Liver Disease (AASLD) for 2016.

*Study Drug (specify drug, strength, total quantity needed to complete study)

CHIP requests the standard one pill per day, fixed-dose combination tablet of Harvoni, 90 mg ledipasvir and 400 mg of sofosbuvir. Treatment will be provided to all 100 participants who we anticipate will complete their regimen. On average the majority of participants who are treatment-naïve with or without cirrhosis will complete the standard 12-week regimen; however, we recognize that some patients will complete their regimen in either 8 or 24 weeks. The pilot will require Harvoni treatment for 100 patients. For the majority of patients completing a 12-week regimen, we request 84 pills per patient for a total 21,000 pills for the 100 patients participating in the demonstration project. For tracking purposes, we request that the Harvoni regimen be presented in one week packaging.

* Mandatory items from the Gilead application

Gilead Contact

Richard W. Presnell, MD, ABIM, AAHIVE
Associate Director, Medical Sciences
2413 W 107th Drive
Westminster, CO 80234-3160
(720) 375-2542 (cell)
(720) 284-8829 (fax)

* Mandatory items from the Gilead application

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* Mandatory items from the Gilead application

Appendix A: Gantt Chart
CHIP's Projected 1.5-Year Pilot Timeline

Key Milestones	2015			2016												2017		
	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M
Planning and Preparation (3 months)																		
UCSF and SCVMC IRB submission approved																		
Project staff are hired, trained, and have jail clearance																		
HCV screening and treatment protocols established																		
Establish partnerships with community clinics and jails																		
Consent Forms and protocols are finalized																		
PAB meetings																		
Pilot Implementation (1 year)																		
Implement HCV screening efforts to inmates																		
Recruit 50 patients from each site (100 total)																		
Provide Harvoni treatment for eligible inmates																		
Provide Intense Patient Navigation Services																		
Close out and Data Analysis (3 months)																		
Evaluate program (w/ UCSF Statistician)																		
Write up program outcomes																		
Est. protocols and additional funding to expand services to ensure sustainability																		

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APPENDIX B: Sponsor Acceptance Letter
San Francisco Study Center

May 4, 2015

Investigator Sponsored Research
Gilead Sciences
ATTN: Phase 4@gilead.com

To Whom It May Concern:

San Francisco Study Center Inc, a nonprofit since 1972 and fiscal sponsor since 1975, is pleased to serve as fiscal sponsor of the Jail Health services / HIV & Integrated Testing Project, a program of the S.F. Department of Public Health, for which Study Center manages a number of projects. Study Center's IRS letter documenting our tax-exemption is attached.

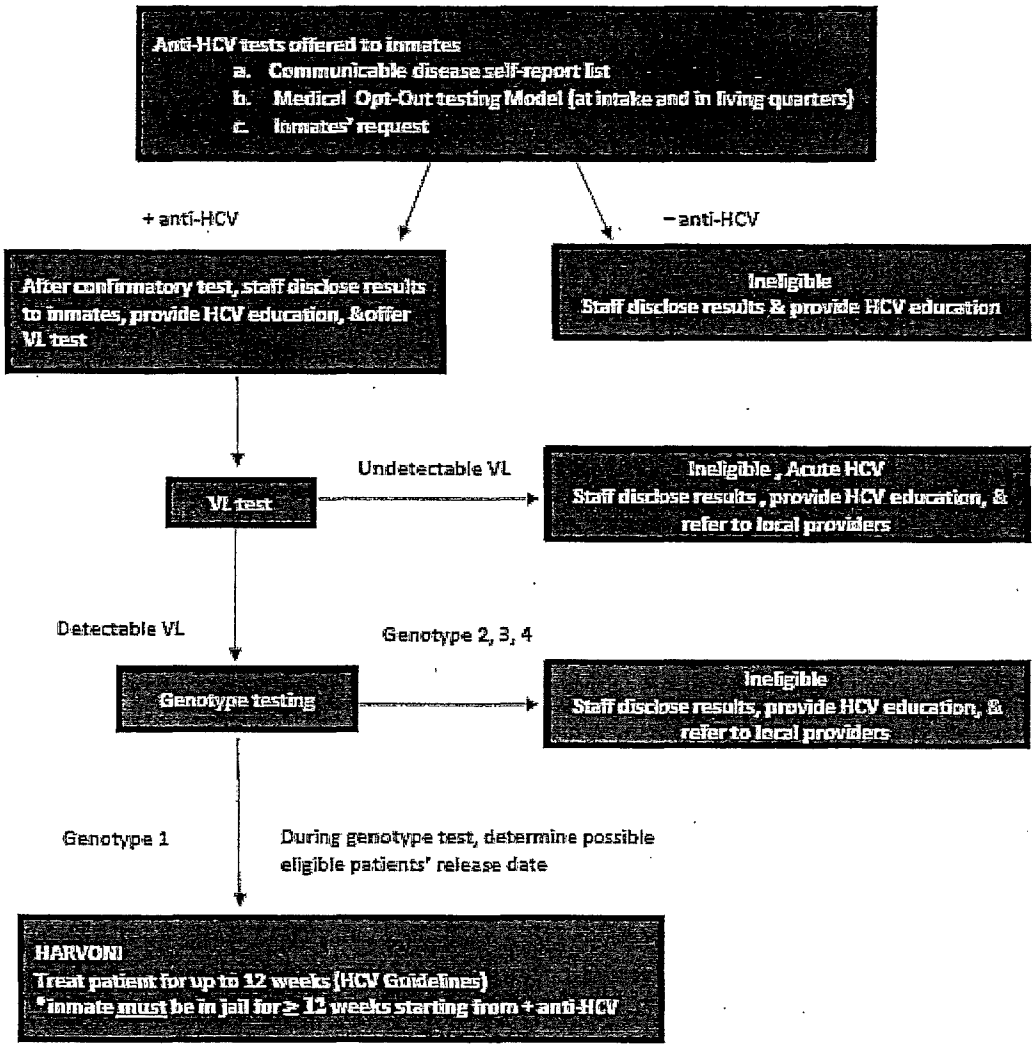
Study Center will manage the finances of this project and meet all reporting requirements.

Sincerely,

Geoffrey Link,
Executive Director

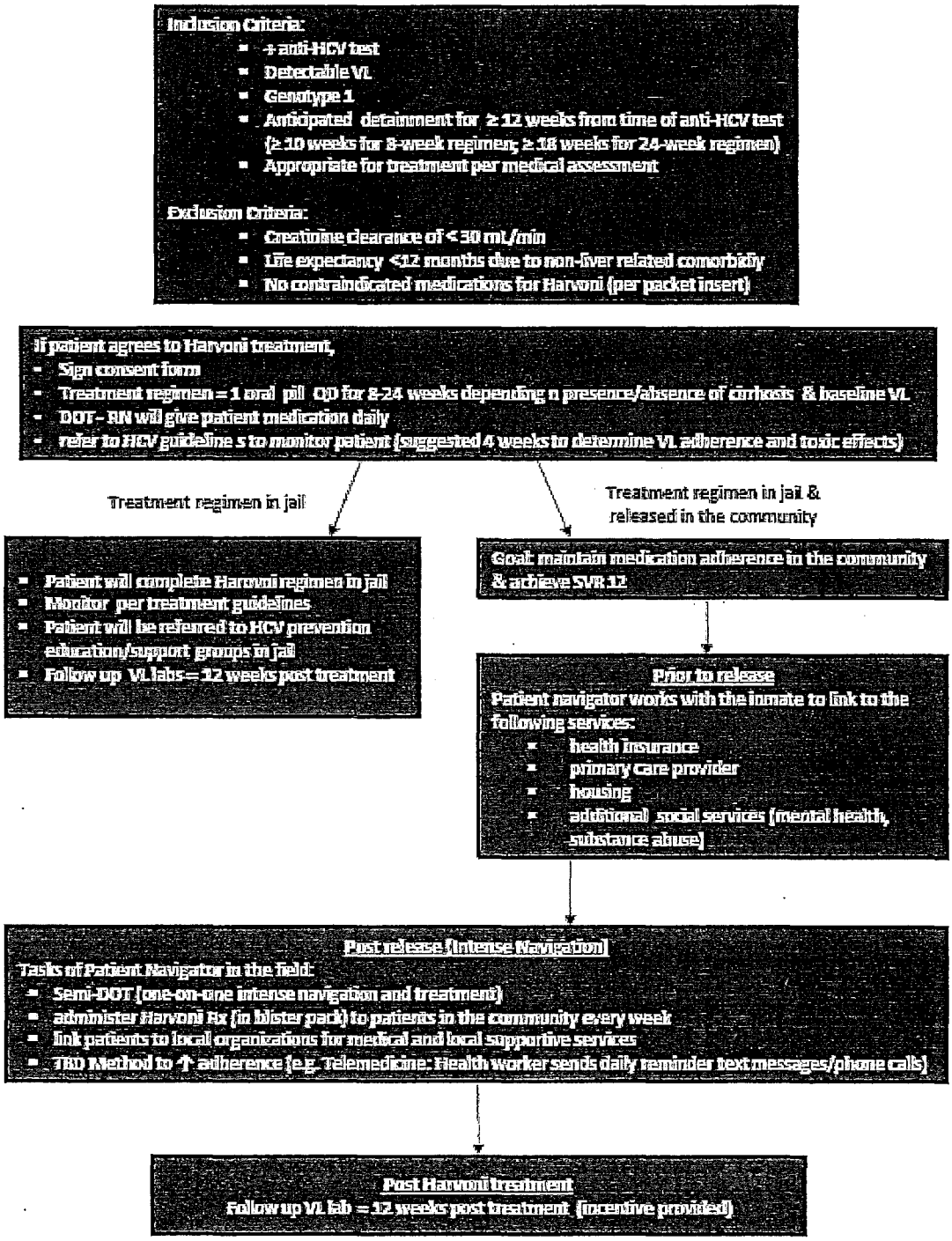
* Mandatory items from the Gilead application

APPENDIX C: HCV SCREENING FLOWCHART



* Mandatory items from the Gilead application

APPENDIX D: HCV TREATMENT FLOWCHART



* Mandatory items from the Gilead application

City and County of San Fr. .cisco

De. .rtment of Public Health

Edwin M. Lee
Mayor

Barbara A. Garcia, MPA
Director of Health

TO: Angela Calvillo, Clerk of the Board of Supervisors

FROM: Barbara A. Garcia, MPA
Director of Health

DATE: October 21, 2015

SUBJECT: Grant Accept and Expend

GRANT TITLE: Curing HCV in Incarcerated Patients- $517,119.17

Attached please find the original and 2 copies of each of the following:

☒ Proposed grant resolution, original signed by Department

☒ Grant information form, including disability checklist -

☒ Budget and Budget Justification

☒ Grant application

☒ Agreement / Award Letter

☐ Other (Explain):

Special Timeline Requirements:

Departmental representative to receive a copy of the adopted resolution:

Name: Richelle-Lynn Mojica Phone: 255-3555

Interoffice Mail Address: Dept. of Public Health, Grants Administration for Community Programs, 1380 Howard St.

Certified copy required Yes ☐ No ☒

(415) 554-2600 101 Grove Street San Francisco, CA 94102-4593

OFFICE OF THE MAYOR
SAN FRANCISCO

EDWIN M. LEE
MAYOR

TO: Angela Calvillo, Clerk of the Board of Supervisors
FROM: Mayor Edwin M. Lee
RE: Accept and Expend Grant- Curing HCV In Incarcerated Patients- $517,119.17
DATE: November 17, 2015

Attached for introduction to the Board of Supervisors is a resolution retroactively authorizing the San Francisco Department of Public Health to accept and expend a grant in the amount of $517,119.17 from Gilead Sciences, Inc. to participate in a program entitled Curing HCV in Incarcerated Patients for the period of October 1, 2015, through March 31, 2017, waiving indirect costs.

Should you have any questions, please contact Nicole Elliott (415) 554-7940.

1 DR. CARLTON B. GOODLETT PLACE, ROOM 200
SAN FRANCISCO, CALIFORNIA 94102-4681
TELEPHONE: (415) 554-6141

File No. 151186

FORM SFEC-126:
NOTIFICATION OF CONTRACT APPROVAL
(S.F. Campaign and Governmental Conduct Code § 1.126)

City Elective Officer Information *(Please print clearly.)*	
Name of City elective officer(s): Members, SF Board of Supervisors	City elective office(s) held: Members, SF Board of Supervisors

Contractor Information *(Please print clearly.)*	
Name of contractor: **San Francisco Study Center**	
Please list the names of (1) members of the contractor's board of directors; (2) the contractor's chief executive officer, chief financial officer and chief operating officer; (3) any person who has an ownership of 20 percent or more in the contractor; (4) any subcontractor listed in the bid or contract; and (5) any political committee sponsored or controlled by the contractor. Use additional pages as necessary. 1) Board – See Attachment 2) N/A 3) N/A 4) N/A	
Contractor address: 1663 Mission Street, 3rd floor, San Francisco, CA 94103	
Date that contract was approved:	Amount of contract: $517,119.17
Describe the nature of the contract that was approved: Hepatitis C testing and treatment for jail based Hep C+ prisoners in two urban jail facilities: San Francisco County Jails and Santa Clara County Jail.	
Comments:	

This contract was approved by (check applicable):

☐ the City elective officer(s) identified on this form

☐ a board on which the City elective officer(s) serves San Francisco Board of Supervisors
Print Name of Board

☐ the board of a state agency (Health Authority, Housing Authority Commission, Industrial Development Authority Board, Parking Authority, Redevelopment Agency Commission, Relocation Appeals Board, Treasure Island Development Authority) on which an appointee of the City elective officer(s) identified on this form sits

_____
Print Name of Board

Filer Information *(Please print clearly.)*	
Name of filer: Angela Calvillo, Clerk of the Board	Contact telephone number: (415) 554-5184
Address: City Hall, Room 244, 1 Dr. Carlton B. Goodlett Place, San Francisco, CA 94102	E-mail: Board.of.Supervisors@sfgov.org

_____ _____
Signature of City Elective Officer (if submitted by City elective officer) Date Signed

_____ _____
Signature of Board Secretary or Clerk (if submitted by Board Secretary or Clerk) Date Signed

San Francisco Study Center

Board of Directors	Staff
John Burks, President	Geoffrey Link, Executive Director
Richard Livingston, Vice President	(includes Fiscal sponsorship inquiries)
Jim McWilliams	Kevin Walsh, Director of Finance
Ben Fong-Torres	John Nuñez, Bookkeeper
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Reiko Homma True	
Tina Tong Yee	
Hazim Elbgal	