

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	Year 2	Year 3	COMMENTS
				2015 (3 months)	2016 (12 months)	2017 (3 months)	
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
	104	\$102.09	\$10,617.36	\$8,643.89	\$79,510.50		Fringe Benefits (SF Study Center) - 34%
	104	\$103.10	\$10,722.40		\$10,617.36		Statistician CSTI (UCSF overhead) - \$102.09 - Hourly @ 10% FTE (hired Jan. 1, 2016)
					\$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^a:	0	\$0.00	\$0.00				All tests and laboratory costs will be covered under SFDPH & Santa Clara Valley Health & Hospital
	0	\$0.00	\$0.00				
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 Expense^e:							
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
	52	\$103.10	\$5,361.20			\$5,361.20	Statistician CSTI (UCSF overhead) - \$103.10 (Hourly @ 10% FTE)
						\$1,793.32	Fringe Benefits (SF Study Center) - 34%
							Fringe Benefits (UCSF) - 33.45%
Other Expenses^f:	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^h:	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			<i>Sponsor/Overhead charge (SF Study Center) - 10% of gross receipts (subtotal)</i>
	1	\$834.00	\$834.00	\$208.50	\$10,017.73	\$2,510.40	<i>Sponsor/Overhead charge (UCSF) for Statistician only - 34% of gross (subcontract)</i>
	4	\$100.00	\$400.00	\$25.00	\$834.00	\$208.50	<i>SF Study Center general liability (prorated for \$834.00 between April 2015 - April 2016)</i>
				\$25.00	\$400.00	\$50.00	<i>SF Study Center employee liability (\$100/ employee x 4 employees)</i>
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

Amount/Proportion Requested from Gilead:

\$517,119.17 SF Study Center sponsor/overhead charges included (10%)

Amount/Proportion Requested/Funded by Outside Sources:

\$0.00

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

^aSpecify 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.

^bFor 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.

^cProvide 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.

^dProvide an explanation of how the IRB fees were calculated and provide a copy of the institutional fee schedule if applicable.

^eSpecify and provide a detailed breakdown for each expense.

^fPublication costs should be listed by abstract and/or slide/poster development, poster printing, manuscript development, etc.

^gCosts 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.

^hProvide a detailed breakdown for any indirect costs and a copy of any institutional policies about the calculation of such costs.

PERSONNEL**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 available 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 Study 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.