Confidential information not subject to disclosure under FOIA or state freedom of information and open records laws.

MASTER FOCUS AGREEMENT

THIS MASTER FOCUS AGREEMENT ("**Agreement**") is entered into as of ______, ("**Effective Date**") by and between Gilead Sciences, Inc., with a principal place of business at 333 Lakeside Drive, Foster City, CA 94404 ("**Gilead**") and Guilford County, with a principal place of business at 1002 Meadowood St. Greensboro, NC 27409 ("**Organization**"). Gilead and Organization are hereafter collectively referred to as "**Parties**" and each may individually be referred to as a "**Party**."

RECITALS

WHEREAS, Gilead is a biopharmaceutical company that researches, develops, manufactures, and markets human pharmaceuticals for certain diseases, including the hepatitis C virus ("**HCV**"), hepatitis B virus ("**HBV**") and the Human Immunodeficiency Virus ("**HIV**");

WHEREAS, a growing body of research shows that opt-out testing can play a strong role in getting more individuals tested, extending earlier and better care to infected individuals, improving quality of life, and promoting better disease management that reduces new infections; and

WHEREAS, in light of the 2006 Centers for Disease Control ("CDC") recommendations for routine opt-out HIV testing, the 2012 CDC recommendations for HCV screening, the US Preventive Services Task Force recommendations for routine HIV, HCV, and HBV screening, and other recognized best practices in HIV, HCV, and HBV screening, Organization desires to develop and promote a replicable model program that embodies best practices in HIV, HCV, and/or HBV screening and linkage to care ("Project"); and

WHEREAS, Gilead desires to provide funds to Organization through its Frontlines of Communities in the United States (FOCUS) Program to financially support such efforts.

NOW, THEREFORE, in consideration of these premises and of the mutual agreements, covenants and conditions of this Agreement, the Parties now agree as follows:

1. PROJECT AWARD, BUDGET AND SERVICES

Gilead may provide funds (each grant of funds, an "Award") to Organization from time to time and subject to the terms and conditions of this Agreement; provided, however, Gilead is not required to grant any Award hereunder. Organization shall be required to submit a proposal, or similar documentation, to Gilead prior to Gilead's approval of any Award. Each proposal shall include Organization's proposed scope and budget ("Budget") for use of the Award. Gilead will notify Organization in writing when an Award has been approved and will describe the anticipated date(s) of disbursement(s) for the Award (such notification, the "Award Letter"). Gilead intends that any Award shall only be used to support Organization's mission of developing and promoting a program that embodies best practices in HIV, HCV, and/or HBV screening and linkage to care and Organization acknowledges and agrees that Award amounts will only be spent by Organization in furtherance of such activities and in accordance with the applicable Budget. Gilead's prior written approval (which may include approval made via email by a representative authorized to bind Gilead) is required before any material change in the applicable Project scope or Budget may be made by Organization.

Any Award Letter must be acknowledged in writing by Organization prior to the disbursement of any Award funds thereunder. After such acknowledgement by Organization, the Award Letter and associated Budget will be incorporated into this Agreement as Exhibit C. The first Award Letter issued to Organization under this Agreement will be designated Exhibit C.1; subsequent Award Letters, if granted, will be designated Exhibit C.2 et. seq.

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Any authorized re-allocation of Budget expenditures requires Gilead's prior written approval if a change is more than 10% of each line item or more than 10% of the total Budget. Staff or personnel allocations may not be changed without Gilead's prior written approval.

2. OBLIGATIONS

- (a) <u>Reporting Obligations</u>. Organization shall submit to Gilead or Gilead's designee (which may include ICFI, Inc.) (i) interim and final reports, (ii) quarterly data reports, and (iii) monthly high level estimated data reports, as instructed by Gilead (each interim report, final report, quarterly data report, and monthly estimated data report, a "**Report**" hereunder). Interim and final Reports shall be submitted by Organization in accordance with the timelines contained within the applicable Award Letter. The interim and final Reports shall include, at a minimum, the following information specific to the Project:
 - A narrative update on progress of the Project;
 - The type and nature of any expenditure of Award amounts to date;
 - An attestation that any expenditure of Award amounts to date, including but not limited to expenditures for travel and full time equivalent ("FTE") time, are (1) accurate and (2) reasonable and necessary to fulfill the Project goals;
 - A description of the Project Data (defined below) provided by Organization to Gilead or Gilead's designee, and confirmation that all applicable Project Data has been submitted to Gilead or Gilead's designee on a monthly basis; and
 - Any other information reasonably requested by Gilead and readily available to Organization related to the Project, the services performed by Organization hereunder or the Award.

If actual Award expenditures for FTE time or travel are below budget, or anticipated to be below budget, at the time of either the interim or final Report, Organization will at Gilead's sole option either: (1) re-allocate Award amounts for other necessary Project-related costs or (2) return unused Award funds to Gilead.

The quarterly data Reports shall be generated by Organization and contain the data listed on <u>Exhibit A</u> attached hereto and incorporated herein ("**Project Data**"). The monthly estimated data Reports shall be generated by Organization and contain the data listed on <u>Exhibit B</u>, attached hereto and incorporated herein.

- (b) <u>Publication Obligations</u>. Organization shall analyze (or have analyzed) the Project Data and, subject to Section 6(d) below, shall use best efforts to (i) present such analyzed Project Data at professional conferences; (ii) publish such analyzed Project Data in a peer-reviewed publication or professional publication; and (iii) publish best practices and lessons learned related to its testing and testing-related services in publicly-available print or web materials. All presentations, publications, or other materials disseminated by Organization under this section 2(b) or under any other section of this Agreement which concern the Project or Project Data shall include the statement "Supported by funding from Gilead Sciences, Inc."
- (c) <u>Summit Obligations.</u> Organization shall attend periodic meetings related to Gilead's FOCUS Program, which includes roundtable discussions regarding various' partners FOCUS projects, best practices regarding testing and linkage to care services, and emerging methods and developments in the field ("**Summit**"). Organization shall participate in the Summit at a location selected by Gilead upon reasonable advanced notice, at Gilead's cost. Organization shall allocate a portion of the

Budget to cover its reasonable travel costs and related expenses to attend the Summit. If actual Summit expenditures for travel costs and related expenses are below budget, Organization will at Gilead's sole option, either: (1) re-allocate Award amounts for other necessary Project-related costs or (2) return unused Award funds to Gilead.

3. REPRESENTATIONS, WARRANTIES AND COVENANTS

- (a) <u>Mutual Representations</u>. The Parties mutually represent, warrant and covenant to each other that:
- (i) Each will comply with all applicable federal, state, and local laws and regulations applicable to the Project, including without limitation, the federal healthcare program anti-kickback statute, 42 U.S.C. § 1320a-7b(b) and
- (ii) The Award and any ancillary Project support are not provided as an inducement or reward for the purchase, use or recommendation of any product manufactured or marketed by Gilead or to promote such products, and Organization shall not promote Gilead products, directly or indirectly.
- (b) <u>Organization Representations</u>. Organization further represents, warrants and covenants to Gilead that:
- (i) Organization has the full right and authority to enter into and to carry out this Agreement and that it has no obligations, commitments or restrictions that limit its ability to do so including, without limitation, as a condition to the receipt of any federal or state funds;
- (ii) Organization is not otherwise required under any contract or agreement with any third party to carry out the activities that are part of the Project subject to the Award;
- (iii) The Project is not of the type requiring Institutional Review Board (IRB) approval or waiver; or alternatively, Organization has obtained, or will obtain prior to undertaking the Project, IRB approval or waiver;
- (iv) Organization will comply with all conditions imposed upon Organization as a recipient of federal and/or state funds, including any obligation to report the receipt of the Award as may be so required and the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and will only transmit Project Data that has undergone de-identification. Organization acknowledges that Gilead is not a covered entity and therefore is not subject to HIPAA;
- (v) If Organization obtains individually identifiable health information about one or more individuals in connection with the Project, Organization will safeguard any and all such individually identifiable health information (as defined under HIPAA), including against disclosure to Gilead (through the submission of Project Data or otherwise), and shall use or disclose said information only as permitted by applicable state and federal laws, including without limitation applicable administrative simplification provisions of HIPAA;
- (vi) No Report shall include any information related to any patient served under the Project in relationship to any Gilead or other pharmaceutical manufacturer's product, or any

information relating to the nature or number of prescriptions for any Gilead or other pharmaceutical manufacturer's products;

- (vii) The Award will only be used in accordance with this Agreement and not for any direct patient care or overhead or general expenses (except as may otherwise be listed in the applicable Budget), the Award amounts, if any, which are allocated in the applicable Budget to personnel costs are an accurate representation of the number of personnel needed to execute the Project, and Award amounts, if any, which are allocated in the applicable Budget to service, upkeep, or warranty costs of Organization's existing diagnostic testing equipment, are reasonably related to the incremental use of the equipment under the Program;
- (viii) Organization will not bill or seek reimbursement from any third parties, including any federal or state health care programs or other federal or state funding sources for any testing kits, lab screenings, equipment, or other items or services to be provided through the use of Award funds pursuant to this Agreement or otherwise in connection with the Project;
- (ix) Organization will not claim as a cost in any cost report submitted to any third party, including any federal or state health care programs or other federal or state funding sources, any equipment, testing kits, or other items or services provided to Organization through the use of Award funds pursuant to this Agreement or otherwise in connection with the Project;
- (x) Organization has not been, and during the term of this Agreement shall not be debarred, excluded or suspended from participation in any federal or state health care program, nor convicted of a crime for which a person can be debarred under 21 U.S.C. § 335a, nor threatened to be debarred or indicted for a crime or otherwise engaged in conduct for which a person can be debarred;
- (xi) Organization understands and agrees that it is solely responsible for all decisions regarding selection of the medical provider(s) to which patients may be linked pursuant to the Project; and
- (xii) Organization understands and agrees that any decisions regarding treatment or treatment referrals are to be made solely by a licensed health care provider in consultation with his or her patient, and that Organization shall not attempt in any manner to influence the choice of therapy in favor of any particular pharmaceutical or other treatment, including without limitation pharmaceuticals manufactured or marketed by Gilead. Various referral options will be available to facilitate patients' needs and preferences.

4. CONFIDENTIAL INFORMATION

"Confidential Information" hereunder shall include, but not be limited to, Gilead's FOCUS Program information, budget details, proposals, agreements, Gilead personnel, standards, and related know-how, research and development data; provided, however, Confidential Information shall not include any information that (a) has become generally available to the public (other than as a result of any unauthorized disclosure by Organization); (b) was or becomes available to Organization on a non-confidential basis from a source other than Gilead, provided such source is not bound by a confidentiality understanding with Gilead or another party; or (c) was independently developed by Organization without use of the Confidential Information (as evidenced by written records). Organization shall indicate thereon that the information is considered to be Gilead's confidential information that is exempt from disclosure, including under the Freedom of Information Act ("FOIA") 5 U.S.C. § 552(b)(4), and if Organization is advised that such information will be released or believes it is legally compelled to disclose any Gilead Confidential Information, Organization shall provide Gilead with prompt notice so that it may seek a

protective order or other appropriate remedy, or waive compliance with the provisions of this Agreement. Organization shall keep Gilead's Confidential Information, and any and all documents or information derived there from, strictly confidential and shall not disclose such information in any manner to any third party, including any other governmental agency or department (federal or state), without Gilead's prior written consent. This Section 4 shall apply during the term of this Agreement and for up to three (3) years from the date of expiration or termination of this Agreement.

5. GOVERNMENT REPORTING OBLIGATIONS

Organization understands and agrees that Gilead may be required to post or report to government entities all amounts disbursed to Organization under this Agreement. Organization further agrees to provide, at Gilead's reasonable request, any information necessary for Gilead to make such required posting or reporting.

In addition, Organization acknowledges that certain payments made by Gilead may be subject to reporting to the federal government and subsequent public disclosure under the U.S. Physician Payment Sunshine Act, 42 U.S.C. § 1320a-7h, and the regulations implemented thereunder, including (i) funds paid to teaching hospitals and (ii) funds used by Organization to make payments or other transfers of value to U.S.-licensed physicians or teaching hospitals. Accordingly, Organization hereby consents to Gilead's disclosure of such information and agrees to provide to Gilead any information necessary for such required reporting.

6. MISCELLANEOUS

- (a) <u>Indemnification</u>. Organization agrees to indemnify, defend and hold harmless Gilead from any and all claims, losses, liabilities, damages, expenses and costs arising out of or in connection with the Project or this Agreement, except to the extent any such claim results from the negligence or willful misconduct of Gilead.
- (b) <u>Inspection</u>. Gilead (or its designee) may, upon thirty (30) days' notice, inspect Organization's books and records as they pertain to the Award. In the event of any such inspection, Organization will take reasonable precautions to avoid the disclosure of any individually identifiable health information. Upon any reasonable request made by Gilead from time to time, Organization shall submit to Gilead any audited financial statements or auditor reports (for the most recently completed fiscal year) that are available.
- (c) Term and Termination. The term of this Agreement will commence on the Effective Date and will continue until terminated in writing in accordance with this Section 6(c). This Agreement may be terminated without cause (i) by Gilead, effective upon thirty (30) days written notice to Organization and (ii) by Organization effective as of the one (1)-month anniversary of Organization's submission of its final Report (pursuant to Section 2(a) above) required under the Award Letter then in effect. Either Party may terminate this Agreement immediately upon the other Party's insolvency, filing of a petition in bankruptcy, making an assignment for the benefit of creditors, becoming subject to any proceeding under bankruptcy or insolvency law, or winding up or liquidation, voluntarily or otherwise. Gilead may immediately terminate the Agreement upon Organization's material breach of the Agreement. Upon any termination, Organization will be required to return to Gilead, within seven (7) days, any Award (or portion of an Award) provided, but not yet expended prior to the date of termination. The termination of this Agreement shall not relieve any Party of its obligations with respect to any obligations which by their terms would reasonably survive.

- (d) <u>Publicity</u>. Organization agrees not to issue (nor instruct its partners or agents to issue) any press release, publication or other general public announcement regarding this Agreement or services provided under this Agreement (including press releases, publications or general public announcements required under Section 2(b) above), without the prior written consent of Gilead. Moreover, any press release, publication or public announcement by Organization or its agents or partners, arising out of this Agreement and/or utilizing the Project Data, shall include the following acknowledgment: "Supported by funding from Gilead Sciences, Inc."
- (e) <u>Gilead Right to Use Project Data</u>. Gilead and its agents shall have a non-exclusive, irrevocable right to use the Project Data for internal research, non-commercial and publication purposes, and Organization shall cooperate with Gilead and its agents in order to fulfill such purposes. Gilead and its agents shall also have an irrevocable right to share the Project Data with certain government entities, including the CDC. In the event Gilead or its agents publish the Project Data (including via publications that combine the Project Data with data from other testing or awareness projects), Gilead shall have the right to attribute Organization's name as a source of such published data.
- (f) <u>Relationship of the Parties</u>. Organization shall at no time hold itself out as an agent, partner, subsidiary or affiliate of Gilead for any purpose and shall have no authority to act on behalf of or bind Gilead to any obligation.
- (g) <u>Governing Law</u>. All questions relating to the execution, interpretation and performance of this Agreement shall be governed by the laws of the State of California.
- (h) <u>Notices</u>. All notices to either Party (each a "Notice") will be in writing, will refer specifically to this Agreement and will be hand delivered or sent by express courier service, costs prepaid to the respective address specified below (or to such other address as may be specified by Notice to the other Party):

If to Gilead, to: Gilead Sciences, Inc.

Attn: Sr. Director, Government Affairs

333 Lakeside Drive Foster City, CA 94404

With a copy to: Gilead Sciences, Inc.

Attn: Commercial Legal 333 Lakeside Drive Foster City, CA 94404

Such Notice will be deemed to be duly provided when received if sent by courier service or when delivered if transmitted by hand delivery.

(i) <u>Entire Agreement, Modification, Assignment and Counterparts</u>. This Agreement constitutes the entire understanding between the Parties and supersedes all prior written or oral proposals or agreements pertaining to the subject matter herein. No modification of this Agreement will be effective unless made in writing and executed by duly authorized representatives of each Party.

Organization may not assign this Agreement without the prior written consent of Gilead. This Agreement may be executed in multiple counterparts, each of which shall be deemed as original, but all of which, when taken together, shall constitute one and the same instrument.

- (j) <u>Severability</u>. If any provision of this Agreement is held invalid, all other provisions of this Agreement shall remain in effect; provided, however, that the invalid provision may be modified by the Parties, an arbitrator or a court of law, as needed to make such provision valid.
- (k) <u>No Subcontractors</u>. Organization shall not subcontract or otherwise delegate any of its obligations under this Agreement without Gilead's prior written consent. Organization shall be responsible for the direction and coordination of any subcontractor and shall ensure the subcontractor's compliance with the terms and conditions of this Agreement. Each subcontractor hereunder shall be retained directly by Organization and no contractual or agency relationship shall be created between Gilead and a subcontractor. Gilead shall have no obligation to pay any subcontractor. Gilead's consent to a subcontractor shall not in any way relieve Organization of any duty or responsibility under this Agreement.
- (1) <u>Survival.</u> The provisions of this Agreement, which by their very nature would continue beyond termination, or expiration of this Agreement, including without limitation, Sections 2, 4, 5, and 6, and any other provision of this Agreement that by its terms would survive expiration or termination, will continue as valid and enforceable rights and obligations of the Parties and survive termination or expiration of this Agreement.
- (m) <u>Publicly Traded Company</u>. Organization acknowledges that Gilead is a publicly traded company and that, in the course of performance under this Agreement, Organization may learn of material, non-public information regarding Gilead. Organization understands that federal and state securities laws prohibit Organization or any other person or entity from purchasing or selling Gilead securities while in possession of any such material, non-public information or from disclosing such information to others. Accordingly, Organization's personnel engaged in performance of the Agreement shall not purchase, sell or advise others to purchase or sell Gilead securities while in possession of any material, non-public information and will not disclose such information to others.
- (n) <u>Headings.</u> The headings used in this Agreement are for convenience only and are not intended to be part of the terms and conditions of this Agreement.

Signature page follows.

IN WITNESS WHEREOF, intending to be legally bound, Organization and Gilead have executed or caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

GILEAD SCIENCES, INC.	GUILFORD COUNTY
Ву:	Ву:
Name: Kacy Hutchison	Name:
Title: Vice President, Government Affairs	Title:
Date:	Date:

Confidential information not subject to disclosure under FOIA or state freedom of information and open records laws.

EXHIBIT A

Project Data

Organization will submit the following Project Data to Gilead or Gilead's designee (which may include ICFI, Inc.), on a quarterly basis:

Aggregate Summary Variables (where applicable to Organization's Project)

All Tests

- Clinic/Site Name
- Month and Year of Project Data
- Data Reporting Quarter
- Unique Number of Patients (clinical settings)

HIV Tests

- Unique Number of Clients/Patients Eligible for HIV Testing (clinical settings)
- Number of HIV Tests Performed
- HIV Test Results of Clients Tested (positive, negative, indeterminate, or no result)
- Number of Clients Testing HIV Positive Linked to Care
- Number of Individuals Testing HIV Positive with Diagnosed Acute Infection (Ag/Ab +, Ab -, HIV RNA + Test Result)

HCV Tests

- Unique Number of Clients/Patients Eligible for HCV Testing (clinical settings)
- Number of Clients Born Between 1945-1965 (Birth Cohort) Tested for HCV Ab
- Number of Clients Born Outside of the Birth Cohort Tested for HCV Ab
- HCV Ab Test Results of Clients Tested (positive, negative, invalid/indeterminate/no result)
- Number of Clients Testing HIV Positive Linked to Care
- HCV RNA Test Results of Clients Tested (positive, negative, invalid/indeterminate/no result)
- Number of Individuals Testing HCV RNA Positive Linked to Care

HBsAg Tests

- Unique Number of Clients/Patients Eligible for HBV Testing (clinical settings)
- Number of HBsAg Tests Performed
- HBsAg Test Results of Clients Tested (positive, negative, invalid/indeterminate/no result)
- Number of Clients Testing HBsAg Positive Linked to Care

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Test-level Variables for Positive Clients/Patients Only (where applicable)

All HIV, HCV Ab, or HBsAg Positive Clients

- Client ID (de-identified in accordance with HIPAA)
- Clinic/Site Name
- Data Reporting Quarter
- Year of Birth of Positive Client/Patients
- Race and Ethnicity of Positive Clients/Patients
- Gender of Positive Clients/Patients

HIV Positive Clients (tested or not tested)

- Previous HIV Test Result
- HIV Test Conducted
- HIV Test Result
- Linkage to Care: First Appointment Kept (Y/N)
- Reasons First Appointment Not Kept
- Possible Mode of Transmission

HCV Antibody Positive Clients (tested or not tested; where applicable)

- Ever Injected Drugs (only for clients not in birth cohort)
- Previous HCV Ab Test Result
- HCV Ab Test Result
- HCV RNA Test Conducted by Partner
- HCV RNA Test Result
- HCV RNA Positive Client/Patient Newly Identified
- HCV RNA Positive Clients/Patients Linked to Medical Care: First Appointment Kept (Y/N)
- Reason First Medical Appointment Not Kept
- HCV Positive (Ab or RNA)/HIV Co-Infection? (Y/N)

HBsAg Positive Clients (tested or not tested)

- Country of Origin has a HBsAg prevalence >= 2%
- Ever injected drugs (only for clients not from country with HBsAg prevalence>=2%)
- HBsAg Test Result
- Linkage to Care: First Appointment Kept (Y/N)
- Reasons First Appointment Not Kept

EXHIBIT B

Monthly Estimated Data Template

HIV (if applicable to proposed scope)	[Month] [Year] Data
# HIV Tests Performed	
# HIV Positive Individuals Identified Through Testing	
# Diagnosed Acute HIV Infections	
# HIV Positive Individuals (identified through testing) Attended First Appointment	
HCV (if applicable to proposed scope)	[Month] [Year] Data
# HCV Ab Tests Performed	
# HCV Ab Positive Individuals Identified Through Testing	
# HCV RNA Tests Performed	
# HCV RNA Positive Individuals Identified Through Testing	
# HCV RNA Positive Individuals (identified through testing) Attended First Appointment	
HBV (if applicable to proposed scope)	[Month] [Year] Data
# HBsAg Tests Performed	
HBsAg Positive Individuals Identified Through Testing	
HBsAg Positive Individuals (identified through testing) Attended First Appointment	