New York State Department of Health AIDS Institute Office of the Medical Director and Health Research Inc.

Request for Applications Grants Gateway # DOH01-AICGL2-2022 RFA Number 18788 Internal Program Number: 21-0003

Clinical Guidelines Program

This is a procurement which encompasses one (1) component. In order to apply for this RFA, eligible applicants must be prequalified in the New York State Grants Gateway <u>and</u> must submit an application via the New York State Grants Gateway.

KEY DATES

RFA Release Date:

Questions Due:

Questions, Answers and Updates Posted: (on or about)

Applications Due:

September 9, 2021

September 23, 2021 by 4:00 PM

October 7, 2021

October 28, 2021 by 4:00 PM

DOH Contact Name & Address:

Laura Russell, Program Manager AIDS Institute Clinical Guidelines Program NYS Department of Health/AIDS Institute Office of the Medical Director Email: <u>AIguidelines@health.ny.gov</u>

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I. INTRODUCTION

The New York State Department of Health AIDS Institute (NYSDOH AI), Office of the Medical Director (OMD) and Health Research Inc. (HRI) announce the availability of \$795,000 annually for five years in state and federal funds to provide a wide range of professional processes and activities associated with the development, dissemination, implementation, and evaluation of clinical practice guidelines. The intent of this RFA is to identify an applicant with the capacity, experience, and expertise to manage the Clinical Guidelines Program to ensure the mission of promoting quality medical care is met.

A. Background/Intent

The NYSDOH AI Clinical Guidelines Program began in the 1980s in response to the clinical management challenges of HIV/AIDS. In recent years, the guidelines program has broadened its scope to meet the needs of the NYSDOH AI's expanded mission of improving the health and well-being of persons with or at risk of HIV, sexually transmitted infections (STIs), and viral hepatitis (HCV), and improving LGBTQ and drug user health. The guidelines program serves as a core component of the NYSDOH AI by providing the clinical recommendations and expert opinion upon which other NYSDOH AI programs are designed, implemented, and evaluated.

The mission of the NYSDOH AI Clinical Guidelines Program is to develop and disseminate practical, evidence-based clinical guidelines that promote quality medical care for people in New York State (NYS) who are living with or are at risk of acquiring HIV, HCV, STIs, or developing substance use dependence. The program aims to inform primary care providers who do not specialize in these topic areas but who are providing care to people affected by them within NYS. This is accomplished through a guideline development methodology which incorporates current research and evidence as well as the breadth of experience of committee members who specialize in HIV, HCV, STIs, and substance use and who know the realities of providing clinical care throughout NYS and in a broad array of clinical settings. The program is committed to publishing guidelines that are used in the real world by busy care providers, who find them to be useful and readily accessible tools with immediate application in daily practice.

The Clinical Guidelines Program strives to adhere to the Institute of Medicine's standards for developing trustworthy clinical practice guidelines. This includes establishing and maintaining transparency by explicitly detailing the process by which a guideline was developed, who was involved, their clinical experience, and disclosure of potential financial and intellectual conflicts of interest. This allows guidelines users to have confidence that the guidelines are largely free from bias and, therefore, trustworthy.

On June 29, 2014, Governor Andrew M. Cuomo detailed a three-point plan to move us closer to the end of the AIDS Epidemic in NYS. The goal of the plan is to achieve the first ever decrease in HIV prevalence in NYS.¹

¹ https://www.health.ny.gov/diseases/aids/ending_the_epidemic/index.htm Clinical Guidelines Program

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The three-point plan includes:

- 1. Identifying persons with HIV who remain undiagnosed and linking them to health care;
- 2. Linking and retaining persons diagnosed with HIV to health care and getting them on anti-HIV therapy to maximize HIV virus suppression so they remain healthy and prevent further transmission; and
- 3. Providing access to Pre-Exposure Prophylaxis (PrEP) for high-risk persons to keep them HIV negative.

The Ending the Epidemic Blueprint was publicly released on April 29, 2015. This document provides recommendations to support the implementation of the three-point plan. The RFA specifically addresses BP#(s):

- BP4: Improve referral and engagement
- BP16: Ensure access to stable housing
- BP18: Health, housing and human rights for LGBT communities
- BP19: Institute an integrated comprehensive approach to transgender health care and human rights
- BP22: Access to care for residents of rural, suburban and other areas of the state
- BP23: Provide comprehensive sexual health education
- BP30: Increase access to opportunities for employment and employment/vocational services

The Ending the Epidemic Blueprint is available on the NYSDOH's website at: www.health.ny.gov/diseases/aids/ending_the_epidemic/docs/blueprint.pdf

Other relevant resources are the National HIV/AIDS Strategy (NHAS) and the New York State Prevention Agenda. The National HIV/AIDS Strategy is a five-year plan that details principles, priorities, and actions to guide our collective national response to the HIV epidemic.² Information on the National HIV/AIDS Strategy and updates to the strategy can be found at: <u>https://www.aids.gov/federal-resources/national-hiv-aids-strategy/overview/</u>. The New York State Prevention Agenda is the blueprint for state and local action to improve the health of New Yorkers in five priority areas and to reduce health disparities for racial, ethnic, disability and low socioeconomic groups, as well as other populations who experience them.³ The New York State Prevention Agenda can be found on the following website:

https://www.health.ny.gov/prevention/prevention_agenda/2019-2024/.

B. Available Funding

Up to \$795,000 in State and HRI funding is available annually to support **one (1) statewide award** through this RFA.

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² National HIV/AIDS Strategy

³ NYS Prevention Agenda 2013-2018: New York State's Health Improvement Plan

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

- An award will be made to the highest scoring applicant.
- If there are an insufficient number of acceptable applications (scoring 70 or above) received from any region, HRI/the NYSDOH AI reserves the right to award the next highest scoring applicant in the range of (60-69).
- If there are an insufficient number of fundable applications HRI/NYSDOH AI reserves the right to re-solicit.
- HRI/the NYSDOH reserves the right to revise the award amounts as necessary due to changes in availability of funding.

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

Current Contractors: If you choose to not apply for funding, the NYSDOH AI highly recommends notifying your community partners of your intent. This will ensure community members and providers are aware of the discontinuation of the program and services.

Ryan White funding is the "*payer of last resort*". Please see Ryan White Guidance for Part B Direct Service Subcontractors (**Attachment 1**) for funding restrictions.

Funds under this RFA are considered dollars of "last resort" and can only be used when there are no options for other reimbursement. Grant funding cannot be used to reimburse for services that are able to be billed to a third party (i.e., Medicaid, ADAP, PrEP-AP, private health insurance, Gilead patient assistance, co-pay assistance programs, etc.). A provider cannot use grant funds in lieu of billing for services to a third party.

II. WHO MAY APPLY

A. Minimum Eligibility Requirements

All applicants must meet the following minimum eligibility requirements:

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- Applicant must be prequalified in the New York State Grants Gateway, if not exempt, on the date applications are due;
- Applicant must be a not-for-profit 501c(3) organization, Academic Institution, not-forprofit Medical Research Institute, not-for-profit Medical Association, or Medical Society; and
- Applicant has submitted Attachment 2 Statement of Assurances signed by the Chief Executive Officer (CEO) or Designee to certify the organization meets all criteria listed on Attachment 2. Attachment 2 should be submitted via the Grants Gateway in the Pre-Submission Uploads section of the online application.

III. PROJECT NARRATIVE/WORK PLAN OUTCOMES

A. Program Model Description

The NYSDOH AI Clinical Guidelines Program encompasses a wide range of professional processes and administrative activities associated with the development and maintenance, dissemination, implementation, and evaluation of clinical practice guidelines which address the medical management and treatment needs of individuals with or at risk of HIV, HCV, and STIs and address drug user and LGBTQ health.

The NYSDOH AI's OMD oversees the Clinical Guidelines Program and ensures the activities within the following components are completed. Applicants should demonstrate their ability in:

1. <u>Guideline Development and Maintenance</u>

The clinical guidelines are developed on a consensus basis using committees of distinguished clinicians from throughout NYS with extensive experience in the topic areas of the program. These committees are composed of representative experts in HIV, HCV, STI, substance use, and LGBTQ care. Each has a chair and vice-chair and functions according to committee by-laws. Guidelines committees meet to develop new guidelines as identified by the NYSDOH AI Medical Director, review and update existing guidelines as necessary to keep information current, address emerging clinical and research developments, and advise the NYSDOH AI on topics for inclusion in guideline content. All guidelines undergo both peer and consumer review.

The management of the peer and consumer reviews and the guidelines committees is the responsibility of the funded applicant. Guidelines committee membership, the workflow of each committee, support of the authors, contact with committee chairs and members as well as guidelines conference calls and meetings are arranged by the funded applicant with approval by the NYSDOH AI. The committees rely on evidence in formulating guidelines recommendations; therefore, for each guideline that is developed, the funded applicant coordinates and ensures the provision of:

- a systematic literature search;
- a systematic evidence review;

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- compilation of evidence related to decision points;
- facilitation of ratings to recommendations; and
- an open and transparent methodology which includes peer, liaison, consumer, and public health reviews.

As guidelines are developed and/or updated every 3 years and as needed, the funded applicant will work with the NYSDOH AI, authors, and committees to consider each important factor that determines a decision and to provide a concise summary of the best available research evidence to inform judgements. Those involved in developing guidelines use their expertise to evaluate the quality of evidence leading to recommendations, balancing between benefits, harms, and burdens, with the views, values and preferences of patients, as well as resource use, feasibility, and acceptability. The funded applicant will work with the committees to address such issues to achieve a thorough model of evidence-based decision making. The funded applicant will ensure that the content of each guideline is rigorously developed using a transparent process that combines scientific evidence, clinical expert knowledge, patient values, and excludes biases from political and commercial entities.

The funded applicant will provide professional editing of all guidelines and manage all editorial and version control processes by which guideline documents are written, reviewed, rated, and translated into electronic media. Applicants should have the demonstrated experience and the necessary methodological expertise to develop clinical guidelines, as well as the capability to manage and direct guidelines committees and subcommittees in activities related to identifying and developing pertinent guidelines topics. Applicants should have experience in project management with groups of medical professionals, capacity to oversee multiple projects simultaneously, and the ability to use subcontractors and specialized consultants as needed to augment internal capacity.

The funded applicant will ensure:

- all medical editorial staff keep abreast of developments in the field of HIV, HCV, STIs, substance use, and LGBTQ health and these developments are reflected in guidelines documents;
- optimized information design and formatting to ensure logical flow and ease of use;
- fidelity across existing related guidelines as new guidelines are developed; and
- archival of all draft versions.

In addition, the funded applicant will work with the NYSDOH AI to advance and refine processes through which evidence is identified, reviewed, and applied to guidelines development.

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2. Guidelines Dissemination

Once a guideline is approved by the NYSDOH AI, it is published on the program's website <u>www.hivguidelines.org</u> along with any companion materials. It is the funded applicant's responsibility to manage and enhance this website. The guidelines produced by the program are designed to be useful and readily accessible tools with immediate application in daily practice; therefore, the website design and function must support this level of ease of use. It is the funded applicant's responsibility, with oversight and approval from the NYSDOH AI, to ensure that the content on <u>www.hivguidelines.org</u> is published in a user-friendly, mobile-friendly format which is visually engaging and up-to-date.

The funded applicant will be responsible for proposing and coordinating activities relating to additional dissemination channels, including growing the program's social media presence and newsletter audience, submitting guidelines to the National Library of Medicine Literature Archive, the creation of podcasts, complementary materials, and other mechanisms to increase the visibility, accessibility, and credibility of the clinical guidelines.

3. **Guideline Implementation**

The funded applicant will be a key participant in a collaborative effort among NYSDOH AI programs to foster the implementation of the NYSDOH AI clinical guidelines. Partnering programs include The NYSDOH AI's Clinical Education Initiative (CEI), which develops and provides clinical trainings based on the clinical guidelines, and the Quality of Care program, which develops clinical performance measures derived from the guidelines. The funded applicant will be responsible for hosting and participating in routine collaborative meetings with these programmatic partners to identify how to work together most effectively to improve clinical care and outcomes.

The funded applicant will be responsible for conducting research and feasibility studies exploring additional mechanisms to aid implementation of the guidelines, such as offering continuing medical education credits (CME) for reading guidelines and showcasing implementation strategies within the guidelines as appropriate.

4. Guideline and Program Evaluation

The funded applicant will be responsible for developing, obtaining NYSDOH AI approval of, and coordinating the implementation of plans to gather feedback from clinicians and/or professional clinical societies in NYS on their use and views of the NYSDOH AI clinical guidelines.

In addition, the funded applicant must propose, and the NYSDOH AI approve, an evaluation plan to ensure that all goals of the program are being met. Key components of this plan will

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5. Administrative and Operational Activities

The funded applicant will be responsible for a wide range of administrative and operational duties to ensure the success of the program, including:

- Schedule, host, facilitate, and document the results of all related (standing or ad-hoc) conference calls and virtual or in-person meetings for each of the activities within the components described above;
- Collect, track, and archive disclosures of relevant financial relationships and confidentiality agreements of program staff, members, authors, liaisons, reviewers, and all other participants in the program;
- Ensure the stipulations outlined in the NYSDOH AI Clinical Guidelines program bylaws (Attachment 3) are followed. This includes developing systems and generating reports to track committee leaders' and members' terms of service, participation, and payment of honoraria;
- Orient guideline committee members, authors, and reviewers to the program and guide them through all development and review processes and procedures;
- Manage development processes and procedures, including developing committee work plans and editorial timetables for guideline completion;
- Schedule, manage logistics and payment for, and facilitate routine Strategic Planning, Steering Committee, and Collaborative Partner meetings;
- Ensure the ongoing management of the <u>www.hivguidelines.org</u> website, including content management system upgrades as needed. Applicants should have substantial experience in website design and management, which includes technological expertise and familiarity with using electronic media effectively, as well as the ability to generate and analyze utilization data; and
- Coordinate and ensure the completion of special projects, including procurement and payment for clinical award plaques; and planning, hosting, and documenting results of program meetings relating to scientific conferences.

Clinical Guidelines Program Page 9 of 10 Funded applicants should include qualified staff in their proposed staffing structures, including those to serve as:

- Principal Investigator
- Project Director
- Medical Editors
- Fiscal Support
- Administrative Support
- Graphic Designer (able to subcontract)
- Web Developer (able to subcontract)

As part of the NYSDOH AI Quality of Care Programs, an overarching goal of the Guidelines Program is to develop and disseminate evidence-based, state-of-the-art clinical practice guidelines that establish a uniform standard of clinical care for all people living with HIV, HCV, STIs, and substance use, regardless of the practice or geographic setting in which they receive care. The Clinical Guidelines Program also supports the NYS ETE Initiative, including the treatment-as-prevention (TasP) strategy, with strong recommendations for increased testing and linkage to care, immediate initiation of antiretroviral therapy, increased awareness of acute HIV infection, and dedicated efforts to maintain HIV viral load suppression.

The funded applicant is expected to achieve the following outcomes:

- An electronically published suite of current, evidence-based, user-friendly clinical guidelines which reflect the priority areas of the NYSDOH AI.
- Increased reach, visibility, accessibility, and credibility of the guidelines.
- Optimized <u>www.hivguidelines.org</u> site design and navigation, combining ease of use with functionality.

Applicants may subcontract components of the scope of work. For those applicants that propose subcontracting, it is preferable to identify subcontracting agencies during the application process. Applicants that plan to subcontract are expected to state in the application the specific components of the scope of work to be performed through subcontracts. Applicants should note that the lead organization (funded applicant) will have overall responsibility for all contract activities, including those performed by subcontractors, and will be the primary contact for the NYSDOH AI. All subcontractors should be approved by the NYSDOH AI.

B. Requirements for the Program

All applicants selected for funding will be required to:

1. Adhere to Health Literacy Universal Precautions (<u>https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/index.html</u>);

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- 2. Adhere to all objectives, tasks and performance measures as listed in Attachment 4 Clinical Guidelines Program work plan;
- Participate in a collaborative process with the NYSDOH AI to assess program outcomes and provide monthly narrative reports describing the progress of the program with respect to: a) implementation, b) success in meeting the Clinical Guidelines Program work plan, c) significant accomplishments achieved, and d) barriers encountered and plans to address noted problems;

IV. ADMINISTRATIVE REQUIREMENTS

A. Issuing Agency

This RFA is issued by the New York State Department of Health AIDS Institute (NYSDOH AI), Office of the Medical Director and Health Research Inc. (HRI). The Department and HRI are responsible for the requirements specified herein and for the evaluation of all applications.

B. Question and Answer Phase

All substantive questions must be submitted in writing via email to:

AIguidelines@health.ny.gov

To the degree possible, each inquiry should cite the RFA section and paragraph to which it refers. Written questions will be accepted until the date posted on the cover of this RFA. This includes Minority and Women Owned Business Enterprise (MWBE) questions and questions pertaining to MWBE forms.

Questions of a technical nature can also be addressed in writing at the email address listed above. Questions are of a technical nature if they are limited to how to prepare your application (e.g., formatting) rather than relating to the substance of the application.

All questions submitted should state "Clinical Guidelines Program RFA" in the subject line.

Some helpful links for questions of a technical nature are below. Questions regarding specific opportunities or applications should be directed to the DOH contact listed on the cover of this RFA.

- <u>https://grantsmanagement.ny.gov/resources-grant-applicants</u>
- Grants Gateway Videos: <u>https://grantsmanagement.ny.gov/videos-grant-applicants</u>
- Grants Gateway Team Email: grantsgateway@its.ny.gov

Clinical Guidelines Program Page 11 of 12 Phone: 518-474-5595 Hours: Monday thru Friday 8am to 4pm (Application Completion, Policy, Prequalification and Registration questions)

 Agate Technical Support Help Desk Phone: 1-800-820-1890 Hours: Monday thru Friday 8am to 8pm Email: <u>helpdesk@agatesoftware.com</u> (After hours support w/user-names and lockouts)

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

This RFA has been posted on the NYS Grants Gateway website at: <u>https://grantsgateway.ny.gov/IntelliGrants_NYSGG/module/nysgg/goportal.aspx</u> and a link provided on the Department's public website at: <u>https://www.health.ny.gov/funding/</u>. The RFA is also posted on HRI's public website at: <u>http://www.healthresearch.org/funding-opportunities.</u>

Questions and answers, as well as any updates and/or modifications, will be posted on the Grants Gateway and HRI's website. All such updates will be posted by the date identified on the cover of this RFA.

C. Letter of Intent

Letters of Intent are not a requirement of this RFA.

D. Applicant Conference

An Applicant Conference will not be held for this project.

E. How to File an Application

Applications must be submitted online via the Grants Gateway by the date and time posted on the cover of this RFA. Reference materials and videos are available for Grantees applying to funding opportunities on the NYS Grants Gateway. Please visit the Grants Management website at the following web address: <u>https://grantsmanagement.ny.gov/</u> and select the "Apply for a Grant" from the Apply & Manage menu. There is also a more detailed "Grants Gateway: Vendor User Guide" available in the documents section under Training & Guidance; For Grant Applicants on this page as well. Training webinars are also provided by the Grants Gateway Team. Dates and times for webinar instruction can be located at the following web address: <u>https://grantsmanagement.ny.gov/live-webinars</u>.

Clinical Guidelines Program Page 12 of 13 To apply for this opportunity:

- 1. Log into the Grants Gateway as either a "Grantee" or "Grantee Contract Signatory".
- 2. On the Grants Gateway home page, click the "View Opportunities" button".
- 3. Use the search fields to locate an opportunity; search by State agency (NYSDOH) or enter the Grant Opportunity name <Clinical Guidelines Program >.
- 4. Click on "Search" button to initiate the search.
- 5. Click on the name of the Grant Opportunity from the search results grid and then select the "APPLY FOR GRANT OPPORTUNITY" button located bottom left of the Main page of the Grant Opportunity.

Once the application is complete, prospective grantees are <u>strongly encouraged</u> to submit their applications at least 48 hours prior to the due date and time. This will allow sufficient opportunity for the applicant to obtain assistance and take corrective action should there be a technical issue with the submission process. Failure to leave adequate time to address issues identified during this process may jeopardize an applicant's ability to submit their application. Both NYSDOH and Grants Gateway staff are available to answer applicant's technical questions and provide technical assistance prior to the application due date and time. Contact information for the Grants Gateway Team is available under Section IV. B. of this RFA.

PLEASE NOTE: Although NYSDOH and the Grants Gateway staff will do their best to address concerns that are identified less than 48 hours prior to the due date and time, there is no guarantee that they will be resolved in time for the application to be submitted and, therefore, considered for funding.

The Grants Gateway will always notify applicants of successful submission. If a prospective grantee does not get a successful submission message assigning their application a unique ID number, it has not successfully submitted an application. During the application process, please pay particular attention to the following:

- Not-for-profit applicants must be prequalified on the due date for this application submission. Be sure to maintain prequalification status between funding opportunities. Three of a not-for-profit's essential financial documents the IRS990, Financial Statement and Charities Bureau filing expire on an annual basis. If these documents are allowed to expire, the not-for-profit's prequalification status expires as well, and it will not be eligible for State grant funding until its documentation is updated and approved, and prequalified status is reinstated.
- Only individuals with the roles "Grantee Contract Signatory" or "Grantee System Administrator" can submit an application.
- Prior to submission, the system will automatically initiate a global error checking process to protect against incomplete applications. An applicant may need to attend to certain parts of the application prior to being able to submit the application successfully. Be sure to allow time after pressing the submit button to clean up any

Clinical Guidelines Program Page 13 of 14 global errors that may arise. You can also run the global error check at any time in the application process. (see p. 68 of the Grants Gateway: Vendor User Guide).

• Grantees should use numbers, letters and underscores when naming their uploaded files. There cannot be any special characters in the uploaded file name. Also, be aware of the restriction on file size (10 MB) when uploading documents. Grantees should ensure that any attachments uploaded with their application are not "protected" or "pass-worded" documents.

The following table will provide a snapshot of which roles are allowed to Initiate, Complete, and Submit the Grant Application(s) in the Grants Gateway.

Role	Create and Maintain User Roles	Initiate Application	Complete Application	Submit Application	Only View the Application
Delegated Admin	Х				
Grantee		Х	Х		
Grantee Contract		Х	Х	Х	
Signatory					
Grantee Payment		Х	Х		
Signatory					
Grantee System		Х	Х	Х	
Administrator					
Grantee View					Х
Only					

PLEASE NOTE: Waiting until the last several days to complete your application online can be dangerous, as you may have technical questions. Beginning the process of applying as soon as possible will produce the best results.

Late applications will not be accepted. Applications will not be accepted via fax, e-mail, hard copy or hand delivery.

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

The Department of Health and HRI reserve the right to:

- 1. Reject any or all applications received in response to this RFA.
- 2. Withdraw the RFA at any time, at the Department's or HRI's sole discretion.
- 3. Make an award under the RFA in whole or in part.
- 4. Disqualify any applicant whose conduct and/or proposal fails to conform to the requirements of the RFA.
- 5. Seek clarifications and revisions of applications.

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

G. Term of Contract

Any State contract resulting from this RFA will be effective only upon approval by the New York State Office of the Comptroller. Any HRI contract resulting from this RFA will be effective only upon approval by HRI. Refer to **Attachment 5** – General Terms and Conditions – Health Research Incorporated Contracts.

It is expected that NYS contracts resulting from this RFA will have the following multi-year time period: **July 1, 2022 – June 30, 2027**. Continued funding throughout this period is contingent upon availability of funding and state budget appropriations. NYSDOH also reserves the right to revise the award amount as necessary due to changes in the availability of funding.

A sample New York State Master Contract for Grants can be found in the Forms Menu once an application to this funding opportunity is started.

HRI funded contracts resulting from this RFA will be for 12-month terms. The anticipated start date of HRI contracts is **July 1, 2022**. However, depending on the funding source, the initial contract term could be for a shorter time period. HRI awards may be renewed for up to four (4) additional annual contract periods based on satisfactory performance and availability of funds. HRI reserves the right to revise the award amount as necessary due to changes in the availability of funding.

H. Payment & Reporting Requirements of Grant Awardees

- 1. The Department may, at its discretion, make an advance payment to not for profit grant contractors in an amount not to exceed twenty-five (25) percent. Due to requirements of the federal funder, no advance payments will be allowed for HRI contracts resulting from this procurement.
- 2. The grant contractor will be required to submit monthly invoices and required reports of expenditures through the Grants Gateway to the State's designated payment office (below) or, if requested by the Department, through the Grants Gateway:

AIDS Institute New York State Department of Health Empire State Plaza Corning Tower Room 259 Albany, NY 12237

Grant contractors must provide complete and accurate billing invoices in order to receive payment. Billing invoices submitted to the Department must contain all information and supporting documentation required by the Contract, the Department and the Office of the State Comptroller (OSC). Payment for invoices submitted by the CONTRACTOR shall only be rendered electronically unless payment by paper check is expressly authorized by the Commissioner, in the Commissioner's sole discretion, due to extenuating circumstances. Such electronic payment shall be made in accordance with OSC's procedures and practices to authorize electronic payments. Authorization forms are available at OSC's website at: http://www.osc.state.ny.us/epay/index.htm, by email at: epayments@osc.state.ny.us/epay/index.htm, by email at: epay

Clinical Guidelines Program Page **16** of **17** Payment of such claims for reimbursement by the State (NYS Department of Health) shall be made in accordance with Article XI-A of the New York State Finance Law. Payment terms will be: Contractor will be reimbursed for actual expenses incurred as allowed in the Contract Budget and Work Plan.

- 3. The funded grant contractor will be required to submit the following periodic reports at the address above or, if requested by the Department, through the Grants Gateway:
 - A monthly narrative addressing program implementation, barriers and accomplishments.

For HRI contracts, contractors will be expected to submit voucher claims and reports of expenditures in the manner that HRI requires. Required forms will be provided with the contract package.

All payment and reporting requirements will be detailed in Attachment D of the final NYS Master Grant Contract. For HRI Contracts, payments and reporting requirements will be detailed in Exhibit "C" of the final contract.

I. Minority & Woman-Owned Business Enterprise Requirements

Pursuant to New York State Executive Law Article 15-A, the New York State Department of Health ("NYSDOH") recognizes its obligation to promote opportunities for maximum feasible participation of certified minority- and women-owned business enterprises and the employment of minority group members and women in the performance of NYSDOH contracts.

In 2006, the State of New York commissioned a disparity study to evaluate whether minority and women-owned business enterprises had a full and fair opportunity to participate in state contracting. The findings of the study were published on April 29, 2010, under the title "The State of Minority and Women-Owned Business Enterprises: Evidence from New York" ("Disparity Study"). The report found evidence of statistically significant disparities between the level of participation of minority- and women-owned business enterprises in state procurement contracting versus the number of minority- and women-owned business enterprises that were ready, willing and able to participate in state procurements. As a result of these findings, the Disparity Study made recommendations concerning the implementation and operation of the statewide certified minority- and women-owned business enterprises program. The recommendations from the Disparity Study culminated in the enactment and the implementation of New York State Executive Law Article 15-A, which requires, among other things, that NYSDOH establish goals for maximum feasible participation of New York State Certified minority- and women-owned business enterprises more things, that NYSDOH establish goals for maximum feasible participation of New York State Certified minority- and women-owned business enterprises.

Business Participation Opportunities for MWBEs

For purposes of this solicitation, the New York State Department of Health hereby establishes a goal of **0%** as follows:

- 1) For Not-for-Profit Applicants: Eligible Expenditures include any subcontracted labor or services, equipment, materials, or any combined purchase of the foregoing under a contract awarded from this solicitation.
- 2) For-Profit and Municipality Applicants: Eligible Expenditures include the value of the budget in total.

The goal on the eligible portion of this contract will be 0% for Minority-Owned Business Enterprises ("MBE") participation and 0% for Women-Owned Business Enterprises ("WBE") participation (based on the current availability of qualified MBEs and WBEs and outreach efforts to certified MWBE firms). A contractor ("Contractor") on the subject contract ("Contract") must document good faith efforts to provide meaningful participation by MWBEs as subcontractors or suppliers in the performance of the Contract and Contractor agrees that NYSDOH may withhold payment pending receipt of the required MWBE documentation. For guidance on how NYSDOH will determine "good faith efforts," refer to 5 NYCRR §142.8.

The directory of New York State Certified MWBEs can be viewed at:

<u>https://ny.newnycontracts.com</u>. The directory is found on this page under "NYS Directory of Certified Firms" and accessed by clicking on the link entitled "Search the Directory". Engaging with firms found in the directory with like product(s) and/or service(s) is strongly encouraged, and all communication efforts and responses should be well documented.

By submitting an application, a grantee agrees to complete an MWBE Utilization plan as directed in **Attachment 6** of this RFA. NYSDOH will review the submitted MWBE Utilization Plan. If the plan is not accepted, NYSDOH may issue a notice of deficiency. If a notice of deficiency is issued, Grantee agrees that it shall respond to the notice of deficiency within seven (7) business days of receipt. NYSDOH may disqualify a Grantee as being non-responsive under the following circumstances:

- a) If a Grantee fails to submit a MWBE Utilization Plan;
- b) If a Grantee fails to submit a written remedy to a notice of deficiency;
- c) If a Grantee fails to submit a request for waiver (if applicable); or
- d) If NYSDOH determines that the Grantee has failed to document good-faith efforts to meet the established NYSDOH MWBE participation goals for the procurement.

In addition, successful awardees will be required to certify they have an acceptable Equal Employment Opportunity policy statement.

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J. Limits on Administrative Expenses and Executive Compensation

On July 1, 2013, limitations on administrative expenses and executive compensation contained within Governor Cuomo's Executive Order #38 and related regulations published by the Department (Part 1002 to 10 NYCRR – Limits on Administrative Expenses and Executive Compensation) went into effect. Applicants agree that all state funds dispersed under this procurement will, if applicable to them, be bound by the terms, conditions, obligations and regulations promulgated by the Department. To provide assistance with compliance regarding Executive Order #38 and the related regulations, please refer to the Executive Order #38 website at: http://executiveorder38.ny.gov.

K. Vendor Identification Number

Effective January 1, 2012, in order to do business with New York State, you must have a vendor identification number. As part of the Statewide Financial System (SFS), the Office of the State Comptroller's Bureau of State Expenditures has created a centralized vendor repository called the New York State Vendor File. In the event of an award and in order to initiate a contract with the New York State Department of Health, vendors must be registered in the New York State Vendor File and have a valid New York State Vendor ID.

If already enrolled in the Vendor File, please include the Vendor Identification number on the application cover sheet. If not enrolled, to request assignment of a Vendor Identification number, please submit a New York State Office of the State Comptroller Substitute Form W-9, which can be found on-line at: <u>hhttps://www.osc.state.ny.us/files/vendors/2017-11/vendor-form-ac3237s-fe.pdf</u>.

Additional information concerning the New York State Vendor File can be obtained on-line at: <u>http://www.osc.state.ny.us/vendor_management/index.htm</u>, by contacting the SFS Help Desk at 855-233-8363 or by emailing at <u>helpdesk@sfs.ny.gov</u>.

L. Vendor Responsibility Questionnaire

The New York State Department of Health strongly encourages that vendors file the required Vendor Responsibility Questionnaire online via the New York State VendRep System. The Vendor Responsibility Questionnaire must be updated and certified every six (6) months. To enroll in and use the New York State VendRep System, see the VendRep System Instructions available at https://www.osc.state.ny.us/state-vendors/vendrep/file-your-vendor-responsibility-questionnaire or go directly to the VendRep system online at https://www.osc.state.ny.us/state-vendors/vendrep/file-your-vendor-responsibility-questionnaire or go directly to the VendRep system online at https://www.osc.state.ny.us/state-vendors/vendrep/file-your-vendor-responsibility-questionnaire or go directly to the VendRep system online at https://www.osc.state.ny.us/state-vendors/vendrep/file-your-vendor-responsibility-questionnaire or go directly to the VendRep system online at https://www.osc.state.ny.us/state-vendors/vendrep/yendrep-system.

Vendors must provide their New York State Vendor Identification Number when enrolling. To request assignment of a Vendor ID or for VendRep System assistance, contact the Office of the State Comptroller's Help Desk at 866-370-4672 or 518-408-4672 or by email at

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itservicedesk@osc.ny.gov.

Applicants opting to complete online should complete and upload the Vendor Responsibility Attestation (**Attachment 7**) of the RFA. The Attestation is located under Pre-Submission uploads and once completed should be uploaded in the same section.

Applicants opting to complete and submit a paper questionnaire can obtain the appropriate questionnaire from the VendRep website, <u>www.osc.state.ny.us/vendrep</u>, and upload it with their Application in the Pre-Submission uploads section in place of the Attestation.

M. Vendor Prequalification for Not-for-Profits

All not-for-profit vendors subject to prequalification are required to prequalify prior to grant application and execution of contracts.

Pursuant to the New York State Division of Budget Bulletin H-1032, dated July 16, 2014, New York State has instituted key reform initiatives to the grant contract process which requires not-for-profits to register in the Grants Gateway and complete the Vendor Prequalification process in order for applications to be evaluated. Information on these initiatives can be found on the <u>Grants Management Website</u>.

Applications received from not-for-profit applicants that have not Registered <u>and</u> are not Prequalified in the Grants Gateway on the application due date listed on the cover of this RFA cannot be evaluated. Such applications will be disqualified from further consideration.

Below is a summary of the steps that must be completed to meet registration and prequalification requirements. The <u>Vendor Prequalification Manual</u> on the Grants Management Website details the requirements and an <u>online tutorial</u> are available to walk users through the process.

1) Register for the Grants Gateway

• On the Grants Management Website, download a copy of the <u>Registration Form for</u> <u>Administrator</u>. A signed, notarized original form must be sent to the NYS Grants Management office at the address provided in the submission instructions. You will be provided with a Username and Password allowing you to access the Grants Gateway.

If you have previously registered and do not know your Username, please email <u>grantsgateway@its.ny.gov</u>. If you do not know your Password, please click the <u>Forgot Password</u> link from the main log in page and follow the prompts.

2) Complete your Prequalification Application

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- Log in to the <u>Grants Gateway</u>. If this is your first time logging in, you will be prompted to change your password at the bottom of your Profile page. Enter a new password and click SAVE.
- Click the *Organization(s)* link at the top of the page and complete the required fields including selecting the State agency you have the most grants with. This page should be completed in its entirety before you SAVE. A *Document Vault* link will become available near the top of the page. Click this link to access the main Document Vault page.
- Answer the questions in the *Required Forms* and upload *Required Documents*. This constitutes your Prequalification Application. Optional Documents are not required unless specified in this Request for Application.
- Specific questions about the prequalification process should be referred to your agency representative or to the Grants Gateway Team at <u>grantsgateway@its.ny.gov</u>.

3) Submit Your Prequalification Application

- After completing your Prequalification Application, click the *Submit Document* <u>Vault Link</u> located below the Required Documents section to submit your Prequalification Application for State agency review. Once submitted the status of the Document Vault will change to *In Review*.
- If your Prequalification reviewer has questions or requests changes you will receive email notification from the Gateway system.
- Once your Prequalification Application has been approved, you will receive a Gateway notification that you are now prequalified to do business with New York State.

<u>Vendors are strongly encouraged to begin the process as soon as possible in order to participate in this opportunity.</u>

N. General Specifications

- 1. By submitting the "Application Form", each applicant attests to its express authority to sign on behalf of the applicant.
- 2. Contractors will possess, at no cost to the State, all qualifications, licenses and permits to engage in the required business as may be required within the jurisdiction where the work specified is to be performed. Workers to be employed in the performance of this contract

Clinical Guidelines Program Page 21 of 22 will possess the qualifications, training, licenses and permits as may be required within such jurisdiction.

- 3. Submission of an application indicates the applicant's acceptance of all conditions and terms contained in this RFA, including the terms and conditions of the contract. Any exceptions allowed by the Department during the Question and Answer Phase (Section IV.B.) must be clearly noted in a cover letter included with the application.
- 4. An applicant may be disqualified from receiving awards if such applicant or any subsidiary, affiliate, partner, officer, agent or principal thereof, or anyone in its employ, has previously failed to perform satisfactorily in connection with public bidding or contracts.
- 5. Provisions Upon Default
 - a. The services to be performed by the Applicant shall be at all times subject to the direction and control of the Department as to all matters arising in connection with or relating to the contract resulting from this RFA.
 - b. In the event that the Applicant, through any cause, fails to perform any of the terms, covenants or promises of any contract resulting from this RFA, HRI and the Department acting for and on behalf of the State, shall thereupon have the right to terminate the contract by giving notice in writing of the fact and date of such termination to the Applicant.
 - c. If, in the judgment of the Department and HRI, the Applicant acts in such a way which is likely to or does impair or prejudice the interests of the State and HRI, the Department and HRI acting on behalf of the State, shall thereupon have the right to terminate any contract resulting from this RFA by giving notice in writing of the fact and date of such termination to the Contractor. In such case the Contractor shall receive equitable compensation for such services as shall, in the judgement of the State Comptroller, have been satisfactorily performed by the Contractor up to the date of the termination of this agreement, which such compensation shall not exceed the total cost incurred for the work which the Contractor was engaged in at the time of such termination, subject to audit by the State Comptroller.
- 6. Applicant must maintain an active registration in the System for Award Management (SAM) at SAM.gov, have no exclusions or delinquent federal debt.

V. COMPLETING THE APPLICATION

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A. Application Format and Content

Please refer to the Grants Gateway: Vendor User Guide for assistance in applying for this procurement through the NYS Grants Gateway. This guide is available on the Grants Management website at: <u>https://grantsmanagement.ny.gov/vendor-user-manual</u>. Additional information for applicants is available at: <u>https://grantsmanagement.ny.gov/resources-grant-applicants</u>.

Also, you must use Internet Explorer (11 or higher) or Microsoft Edge to access the Grants Gateway. Using Chrome or Firefox causes errors in the Work Plan section of the application.

Please respond to each of the sections described below when completing the Grants Gateway online application. Your responses comprise your application. Please respond to all items within each section. When responding to the statements and questions, be mindful that application reviewers may not be familiar with the agency and its services. Therefore, answers should be specific, succinct and responsive to the statements and questions as outlined.

All applicants are required to complete and upload **Attachment 8** -Application Cover Page. Attachment 8 should be submitted via the Grants Gateway in the Pre-Submission Uploads section of the online application.

Application Format

1.	Program Abstract	Not Scored	
2.	Community and Agency Description	Maximum Score:	10 points
3.	Program Design and Implementation	Maximum Score:	70 points
4.	Budget and Justification	Maximum Score:	20 points
	-		100 points

1. Program Abstract

2.

Applicants should provide a program abstract with the following information:

- 1a) Describe the proposed program. Include what will be completed and how.
- 1b) What are the project goals and objectives?

Community and Agency Description

- 1c) What types of outcomes does your organization expect to achieve? How will success be measured?
- 2a) Describe your organization's qualifications, strengths, partnerships, and experience Clinical Guidelines Program Page 23 of 24

Not Scored

Total 10 Points

related to the proposed program model.

2b) Describe the outcomes achieved as a result of any prior grants for clinical guideline development that your organization has received.

3. Program Design and Implementation

Total 70 Points

3a) Referring to Section III, Project Narrative/Work Plan Outcomes and the Clinical Guidelines Program work plan (Attachment 4), describe how your organization will implement a program that meets each of the Program and Staffing Requirements of this RFA. Please be sure to specifically address how your organization will implement the tasks outlined in each objective of the Clinical Guidelines Program work plan (Attachment 4), including an outline of the processes involved, the resources needed, who is involved, and their area of expertise:

Objective 1: Develop new clinical guidelines relevant to the NYSDOH AI topic areas Objective 2: Ensure that existing guidelines are kept up to date Objective 3: Widely disseminate guideline content to clinical audiences in NYS & beyond Objective 4: Foster implementation of NYSDOH AI guidelines Objective 5: Evaluate Guidelines usage Objective 6: Evaluate performance of the program

Applicants are required to complete Attachment 9 - Agency Capacity and Staffing Information. Include any proposed in-kind staff. Attachment 9 can be found in the Pre-Submission uploads section of the Grants Gateway online application.

- 3b) Describe any innovative activities or strategies you plan to use in your program.
- 3c) What are your program's indicators for success? How will you use them to drive program improvement? Please be specific.
- 3d) Describe your organization's readiness to undertake program activities in a timely fashion.
- 3e) What challenges do you anticipate encountering with meeting the program requirements outlined in the Clinical Guidelines Program work plan (Attachment 4) and how will you address them?
- 3f) Describe the methodology your program would utilize in the development and updating of trustworthy clinical guidelines.

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- 3g) How will your program ensure that the website design and function support a high level of ease of use and will present the guidelines as visually engaging, readily accessible, up-to-date tools with immediate application in daily practice?
- 3h) How will your program explore additional mechanisms, such as CME, to aid implementation of the guidelines?
- 3i) Describe the plan for program evaluation and how your program will ensure that all goals of the program are being met.

4. Budgets and Justifications

Total 20 Points

Complete and submit a budget following these instructions:

- 4a) Applicants are instructed to prepare an annual budget based on the maximum award as listed for the region in which they are applying. The budget for year one (July 1, 2022 June 30, 2023) must be entered into the Grants Gateway. Refer to Grants Gateway Expenditure Budget Instructions Attachment 10. All budget lines should be calculated as whole dollar amounts. All costs should be related to the proposed activities, as described in the application narrative and work plan, and should be justified in detail. All costs should be reasonable and cost-effective. Contracts established resulting from the RFA will be cost reimbursable.
- 4b) For staff listed in the Personal services (Salary and Fringe) section of the budget, include a breakdown of the total salary needs for staff. Indicate how the positions relate to program implementation. Applicants are instructed to include a justification for each of the requested FTEs and for the fringe benefits requested.
- 4c) For each item listed under Non-Personal services, describe how it is necessary for program implementation. Non-Personal services include: Contractual, Travel, Equipment, Space/Property & Utilities, Operating Expenses and Other costs.
- 4d) For the last three (3) years, does your organization's Statement of Activities from your yearly audit show that revenues exceeded expenses or expenses exceeded revenue? If the expenses exceeded revenues, please describe both the cost reduction plan and the deficit reduction plan that will correct this. Please attach the Statement of Activities from your yearly audit for the last three (3) years. The Statement of Activities must show total support and revenue and total expenditures. The Statement of Activities is required to be uploaded in the Pre-Submission uploads section of the Grants Gateway online application as **Attachment 11**.
- 4e) Applicants are required to upload a copy of their agency Time and Effort policy as Attachment 12 in the Pre-Submission uploads section of the Grants Gateway online application.

Clinical Guidelines Program Page 25 of 26 4f) Describe the specific internal controls your agency uses to comply with the Federal Uniform Guidance (2 CFR 200).

4g) Funding requests must adhere to the following guidelines:

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

5. Work Plan

For the Grants Gateway **Work Plan Project Summary**, applicants are instructed to insert the Project Summary as it is listed in Work Plan Attachment 4. In the Grants Gateway **Work Plan Organizational Capacity** section, applicants are instructed to list this as "not applicable." Any additional Project Summary or Organizational Capacity entered in these areas <u>will not</u> be considered or scored by reviewers of your application.

Funded applicants will be held to the Objective, Tasks and Performance Measures as listed in Attachment 4: Work Plan. Applicants are <u>not</u> required to enter any Objectives, Tasks or Performance Measures into the Grants Gateway Work Plan.

It is the applicant's responsibility to ensure that all materials to be included in the application have been properly prepared and submitted. Applications must be submitted via the Grants Gateway by the date and time posted on the cover of this RFA. The value assigned to each section is an indication of the relative weight that will be given when scoring your application.

B. Freedom of Information Law

All applications may be disclosed or used by NYSDOH to the extent permitted by law.

Clinical Guidelines Program Page 26 of 27 NYSDOH may disclose an application to any person for the purpose of assisting in evaluating the application or for any other lawful purpose. All applications will become State agency records, which will be available to the public in accordance with the Freedom of Information Law. **Any portion of the application that an applicant believes constitutes proprietary information entitled to confidential handling, as an exception to the Freedom of Information Law, must be clearly and specifically designated in the application.** If NYSDOH agrees with the proprietary claim, the designated portion of the application will be withheld from public disclosure. Blanket assertions of proprietary material will not be accepted, and failure to specifically designate proprietary material may be deemed a waiver of any right to confidential handling of such material.

C. Review & Award Process

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

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

In the event of a tie score, the applicant with the highest score for Section 3 - Program Design and Implementation - will receive the award.

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

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

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

Clinical Guidelines Program Page 27 of 28 To request a debriefing, please send an email to Laura Russell at <u>Alguidelines@health.ny.gov</u>. In the subject line, please write: *Debriefing Request Clinical Guidelines Program RFA*.

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

VI. ATTACHMENTS

Please note that certain attachments are accessed under the "Pre-Submission Uploads" section of an online application and are not included in the RFA document. In order to access the online application and other required documents such as the attachments, prospective applicants must be registered and logged into the NYS Grants Gateway in the user role of either a "Grantee" or a "Grantee Contract Signatory".

- Attachment 1: Ryan White Guidance for Part B Direct Service Subcontractors**
- Attachment 2: Statement of Assurances*
- Attachment 3: NYSDOH AI Clinical Guidelines program bylaws**
- Attachment 4: Clinical Guidelines Program Work Plan**
- Attachment 5: HRI General Terms and Conditions**
- Attachment 6: Minority & Women-Owned Business Enterprise Requirement Forms *
- Attachment 7: Vendor Responsibility Attestation *
- Attachment 8: Application Cover Page*
- Attachment 9: Agency Capacity and Staffing Information*
- Attachment 10: Grants Gateway Expenditure Budget Instructions**
- Attachment 11: Statement of Activities for past three (3) years*
- Attachment 12: Agency Time & Effort Policy*

*These attachments are located / included in the Pre-Submission Upload section of the Grants Gateway online Application.

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

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ATTACHMENT 1 - RYAN WHITE GUIDANCE FOR PART B DIRECT SERVICE SUBCONTRACTORS

This guidance sets forth requirements related to AIDS Institute Ryan White Part B contracts as stipulated in the Ryan White HIV/AIDS Treatment Extension Act and as mandated by HRSA policy and New York State policy. The following information provides guidance for contractors in developing budgets and work plans. Ryan White Part B contracts <u>must</u> adhere to these requirements. This guidance includes information on allowable services, client eligibility, time and effort reporting, administration, and payer of last resort requirements. Please note that these policies may not be applicable to Ryan White Part A contracts administered by PHS.

Ryan White Service Categories

The Ryan White law limits the persons eligible for Ryan White services and limits the services that are allowable with Ryan White funds. Activities supported and the use of funds appropriated under the law must be in accordance with legislative intent, federal cost principles, and program-specific policies issued by the federal Health Resources and Services Administration (HRSA). HRSA policy related to Ryan White Parts A and B states that no service will be supported with Ryan White funds unless it falls within the legislatively defined range of services. In addition, the law stipulates that Ryan White is the "payer of last resort" (see payer of last resort section on page 4).In conducting program planning, developing contracts, and overseeing programs, you must comply with legislative intent and HRSA policy regarding allowable services and payer of last resort requirements.

Ryan White funded medical and support services must be provided in settings that are accessible to low income individuals with HIV disease.

By receiving Part B funds, the contractor agrees to participate, as appropriate, in Ryan White HIV/AIDS Treatment Extension Act initiatives. The contractor agrees that such participation is essential in meeting the needs of clients with HIV as well as achieving the overall goals and objectives of the Ryan White HIV/AIDS Treatment Extension Act.

Ryan White Part B funds may be used to support the following services: **CORE SERVICES**

- 1. Mental health services for HIV-positive persons. Psychological and psychiatric treatment and counseling services offered to individuals with a diagnosed mental illness, including individual and group counseling, based on a detailed treatment plan, provided by mental health professionals licensed by the NYS Department of Education and the Board of Regents to practice within the boundaries and scope of their respective profession. This includes Psychiatrists, Psychologists, Psychiatric Nurse Practitioners, Masters prepared Psychiatric Registered Nurses, and Licensed Clinical Social Workers. All mental health services must be provided in accordance with the AIDS Institute Mental Health Standards of Care.
- 2. Medical case management services (including treatment adherence) are a range of client-centered services that link clients with health care, psychosocial, and other services. The coordination and follow-up of medical treatments are key components of medical case management. These services ensure timely and coordinated access to medically appropriate levels of health and support services and continuity of care, through ongoing assessment of the client's and other key family members' needs and personal support systems. Medical case management includes the provision of treatment adherence counseling to ensure readiness for, and adherence to, complex HIV/AIDS treatments. Key activities include (1) initial assessment of service needs; (2) development of a comprehensive, individualized service plan; (3) coordination of services required to implement the plan; (4) client monitoring to assess the efficacy of the plan; and (5) periodic reevaluation and adaptation of the care plan at least every 6 months, as necessary during the enrollment of the client. It includes client-specific advocacy and/or review

Clinical Guidelines Program Page 29 of 30 of utilization of services. This includes all types of case management including face-to-face, phone contact, and any other forms of communication. Medical case management services must be provided by trained professionals who provide a range of client-centered services that result in a coordinated care plan which links clients to medical care, psychosocial, and other services. Medical case management may be provided in a variety of medical settings, including community health centers, County Departments of Health, hospitals, or other Article 28 facilities. All medical case management services must be provided in accordance with AIDS Institute medical case management standards.

SUPPORT SERVICES, defined as services needed to achieve outcomes that affect the HIV-related clinical status of a person with HIV/AIDS. Support services must be shown to improve clinical outcomes. Support services must facilitate access to care. Allowable support services are:

- **3.** Case management (non-medical) includes the provision of advice and assistance in obtaining medical, social, community, legal, financial, and other needed support services. Non-medical case management does not involve coordination and follow-up of medical treatments, as medical case management does. In accordance with HRSA HAB policy notice 07-04, this includes transitional case management for incarcerated persons as they prepare to exit the correctional system as part of effective discharge planning, or who are in the correctional system for a brief period, which would not include any type of discharge planning. All non-medical case management services must be provided in accordance with AIDS Institute non-medical case management standards.
- **4. Emergency financial** Ryan White HIV/AIDS Program funds may be used to provide Emergency Financial Assistance (EFA) as an allowable support service.
 - a. The decision-makers deliberately and clearly must set priorities and delineate and monitor what part of the overall allocation for emergency assistance is obligated for transportation, food, essential utilities, and/or prescription assistance. Careful monitoring of expenditures within a category of "emergency assistance" is necessary to assure that planned amounts for specific services are being implemented, and to indicate when reallocations may be necessary.
 - b. In addition, Grantees and planning councils/consortia must develop standard limitations on the provision of Ryan White HIV/AIDS Program funded emergency assistance to eligible individuals/households and mandate their consistent application by all contractors. It is expected that all other sources of funding in the community for emergency assistance will be effectively utilized and that any allocation of Ryan White HIV/AIDS Program funds to these purposes will be the payer-of-last-resort, and for limited amounts, limited use and limited periods of time
- 5. Food bank/home-delivered meals Food and Meal Services assist with improving the nutrition status of the client while they develop the necessary skills to make appropriate food choices that will improve and/or maintain their health status. Nutrient dense, well balanced, and safe meals and food tailored to the specific dietary needs of PLWH/A can assist in maximizing the benefits of medical interventions and care. The food and meal services include home-delivered meals, congregate meals, pantry bags, and food gift cards/vouchers. Meals and pantry bags must provide culturally acceptable foods based on knowledge of the food habits and preferences of the target populations.
- 6. Health education/risk reduction -HIV education and risk reduction services include short term individual and/or group level activities to address medical and/or health related education intended to increase a client's knowledge of and participation in their health care, address secondary HIV prevention, improve health, and decrease the risk of transmission of HIV. Education and risk reduction services should be structured to enhance the knowledge base,

Clinical Guidelines Program Page 30 of 31 health literacy and self-efficacy of HIV-infected persons in accessing and maintaining HIV medical services and staying healthy. Recreational and socialization activities are not included in this category.

- 7. Housing services are the provision of short-term assistance to support emergency, temporary or transitional housing to enable an individual or family to gain or maintain medical care. Housing-related referral services include assessment, search, placement, advocacy, and the fees associated with them. Eligible housing can include both housing that does not provide direct medical or supportive services and housing that provides some type of medical or supportive services such as residential mental health services, foster care, or assisted living residential services.
- 8. Linguistic services include interpretation/translation services (both written and oral), provided to HIV- infected individuals (including non-English speaking individuals, and those who are deaf or hard of hearing) for the purpose of ensuring the client's access to medical care and to Ryan White fundable support services that have a direct impact on primary medical care. Funded providers must ensure linguistic services are provided by a qualified professional interpreter.
- 9. Medical Transportation services include conveyance services provided, directly or through voucher, to an eligible client so that he or she may access HIV-related health and support services intended to maintain the client in HIV/AIDS medical care. If this contract is funded under Catalog of Federal Domestic Assistance Number 93.917 or 93.915, the contractor certifies that it will provide transportation services for eligible clients to medical and support services that are linked to medical outcomes associated with HIV clinical status. Transportation should be provided through: A contract(s) with a provider(s) of such services; Voucher or token systems, Mileage reimbursement that enables individuals to travel to needed medical or other support services may be supported with Ryan White HIV/AIDS Program funds, but should not in any case exceed the established rates for Federal Programs. Federal Joint Travel Regulations provide further guidance on this subject; Use of volunteer drivers (through programs with insurance and other liability issues specifically addressed); or, Purchase or lease of organizational vehicles for client transportation programs. Note: Grantees must receive prior approval for the purchase of a vehicle.
- 10. Outreach services are programs that have as their principal purpose identification of people who know their status so that they may become aware of, and may be enrolled in care and treatment services, NOT HIV counseling and testing or HIV prevention education. Outreach programs must be planned and delivered in coordination with local HIV prevention outreach programs to avoid duplication of effort; be targeted to populations known through local epidemiologic data to be at disproportionate risk for HIV infection; be conducted at times and in places where there is a high probability that individuals with HIV infection will be reached; and be designed with quantified program reporting that will accommodate local effectiveness evaluation.
- **11. Psychosocial support services** are the provision of support and counseling activities, child abuse and neglect counseling, HIV support groups that improve medical outcomes, caregiver support, and bereavement counseling. Includes nutrition counseling provided by a non-registered dietitian but excludes the provision of nutritional supplements.
- 12. Referral for health care/supportive services is the act of directing a client to a service in person or through telephone, written, or other type of communication. Referrals may be made within the non-medical case management system by professional case managers, informally through support staff, or as part of an outreach program.
- **13. Treatment adherence counseling** Short term individual and/or group level activities used to provide HIV/AIDS treatment information, adherence counseling, monitoring, and other strategies to support clients in readiness to begin ARV treatment or maintain maximal

Clinical Guidelines Program Page 31 of 32 adherence to prescribed HIV/AIDS treatment. Treatment adherence counseling activities are provided by non-medical personnel outside of the medical case management and clinical setting. The ultimate goal of treatment education is for a consumer to self-manage their own HIV/AIDS-related care. Self-management is the ability of the consumer to manage their health and health care autonomously, while working in partnership with their physician.

Ryan White funds may also be used to support training of providers delivering allowable services that is intended to improve medical outcomes and consumer education/training that is intended to improve medical outcomes.

Payer of Last Resort

- Ryan White is payer of last resort. The Ryan White HIV/AIDS Treatment Extension Act requires that "...the State will ensure that grant funds are not utilized to make payments for any item or service to the extent that payment has been made or can reasonably be expected to be made with respect to that item or service under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or by an entity that provides health services on a prepaid basis. "DSS program policy guidance No. 2 further states that at the individual client level, grantees and/or their subcontractors are expected to make reasonable efforts to secure other funding instead of Ryan White whenever possible. Ryan White funding may only be used for services that are not reimbursable by Medicaid, ADAP Plus or other third-party payers.
- The Contractor shall (i) maintain policies and staff training on the requirement that Ryan White be the payer of last resort and how that requirement is met; (ii) screen each client for insurance coverage and eligibility for third party programs, assist clients in applying for such coverage and document this in client files; and (iii) carry out internal review of files and billing system to ensure Ryan White resources are used only when a third party payer is not available.
- The Contractor shall (i) have billing, collection, co-pay and sliding fee policies that do not act as a barrier to providing services regardless of the clients ability to pay and (ii) maintain file of individuals refused services with reasons for refusal specified and any complaints from clients with documentation of complaint review and decision reached.
- The Contractor shall ensure that policies and procedures classify veterans receiving VA health benefits as uninsured, thus exempting these veterans from the payer of last resort requirement.

Medicaid Certification & Program Income

- Contractors that provide Medicaid-eligible services pursuant to this agreement shall (i) participate in New York State's Medicaid program; (ii) maintain documentation of their Medicaid certification; (iii) maintain file of contracts with Medicaid insurance companies; and (iv) document efforts to obtain Medicaid certification or request waiver where certification is not feasible.
- The Contractor shall bill, track and report to HRI all program income (including drug rebates) pursuant to this agreement that are billed and obtained. Report of program income will be documented by charges, collections and adjustment reports or by the application of a revenue allocation formula.

Clinical Guidelines Program Page 32 of 33 • The Contractor shall (i) establish policies and procedures for handling Ryan White revenue including program income; (ii) prepare a detailed chart of accounts and general ledger that provide for the tracking of Ryan White revenue; and (iii) make the policies and process available for granted review upon request.

Client Charges

The Ryan White HIV/AIDS Program legislation requires grantees and subgrantees to develop and implement policies and procedures that specify charges to clients for Ryan White funded services. These policies and procedures must also establish sliding fee scales and discount schedules for clients with incomes greater than 100% of poverty. The legislation also requires that individuals be charged no more than a maximum amount (cap) in a calendar year according to specified criteria.

Each subcontractor may adopt the following policy for use in their policies and procedures in order to satisfy this legislative requirement.

All clients receiving Ryan White Part B services must meet the following income eligibility requirements. Financial eligibility is based on 500% of the Federal Poverty Level (FPL). Clients above 500% of FPL are not eligible for services. FPL varies based on household size and is updated semi-annually. Financial eligibility is calculated on the gross income available to the household:

- If an individual's income is less than or equal to 100% of the Federal Poverty Level (FPL), the individual may not be charged for services.
- For individuals with income from 101% to 200% of the FPL, a nominal fee of \$5 will be charged per service visit. Cumulative charges in a calendar year can be no more than 5% of the individual's annual gross income. Once the 5% cap is reached, the individual may no longer be charged for services.
- For individuals with incomes from 201% to 300% of the FPL, a nominal fee of \$7 will be charged per service visit. Cumulative charges in a calendar year can be no more than 7% of the individual's annual gross income. Once the 7% cap is reached, the individual may no longer be charged for services.
- For individuals with income over 300% of the FPL, a nominal fee of \$10 will be charged per service visit. Cumulative charges in a calendar year can be no more than 10% of the individual's annual gross income. Once the 10% cap is reached, the individual may no longer be charged for services.

The following discounted fee schedule shall be applied to all individuals receiving a Ryan White Part B service as follows:

- For individuals with income from 101% to 200% of the FPL, a discount of \$5 will be applied to each charge per service visit.
- For individuals with income from 201% to 300% of the FPL, a discount of \$7 will be applied to each charge per service visit.
- For individuals with income over 300% of the FPL, a discount of \$10 will be applied to each charge per service visit.

Services must be provided to eligible clients without regard to either the ability of the individual to pay for such services or the current or past health conditions of the individuals to be served.

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Time and Effort Reporting

Contractors must have systems in place to document time and effort of direct program staff supported by all federal funds. New federal contractors must submit their written policies related to time and effort to HRI for approval. Most often, such systems take the form of a time sheet entry. These time and effort reporting procedures must clearly identify the percentage of time each staff person devotes to contract activities in accordance with the approved budget. The percent of effort devoted to the project may vary from month to month. The employee's time sheet must indicate the percent of effort the employee devotes to each particular project for a given time period. The effort recorded on the time sheet must reflect the employee's funding sources, and the percent of effort recorded for Ryan White funds must match the percent of the employee's time must be documented. In cases where the percentage of effort of contract staff changes during the contract period, contractors must submit a budget modification request to the AIDS Institute.

On audit, contractors will be expected to produce this documentation. Failure to produce this documentation could result in audit disallowances. HRI also has the right to request back-up documentation on any vouchers if they choose to do so. Only indirect staff is not subject to time and effort reporting requirements. Such staff must be included in the indirect costs line, rather than in the salaries section.

Quality

Ryan White Part B contractors are expected to participate in quality management activities as contractually required, at a minimum compliance with relevant service category standards of care and collection and reporting of data for use in measuring performance. Quality management activities should incorporate the principles of continuous quality improvement, including agency leadership and commitment, staff development and training, participation of staff from all levels and various disciplines, and systematic selection and ongoing review of performance criteria, including consumer satisfaction.

HRSA National Monitoring Standards

The National Monitoring Standards (Standards) are designed to help Ryan White HIV/AIDS Program Part A and B (including AIDS Drug Assistance Program) grantees meet federal requirements for program and fiscal management, monitoring, and reporting to improve program efficiency and responsiveness. Requirements set forth in other sources are consolidated into a single package of materials that provide direction and advice to grantees for monitoring both their own work and the performance of service providers. The Standards consolidate existing HRSA/HAB requirements for program and fiscal management and oversight based on federal law, regulations, policies, and guidance documents.

The Standards were developed by the Division of Service Systems (DSS) within the Health Resources and Services Administration's HIV/AIDS Bureau (HRSA/HAB) in response to several Office of Inspector General (OIG) and Government Accountability Office (GAO) reports. These reports identified the need for a specific standard regarding the frequency and nature of grantee monitoring of subgrantees and a clear HRSA/HAB Project Officer role in monitoring grantee oversight of subgrantees.

Grantees and Subgrantees are required to comply with the Standards as a condition of receiving Ryan White Part A and Part B funds. The Standards can be accessed by visiting: http://www.hab.hrsa.gov/manageyourgrant/granteebasics.html

Administration

The Ryan White legislation imposes a cap on contractor administration. The legislative intent is to fund

Clinical Guidelines Program Page 34 of 35 services and keep administrative costs to a minimum. Contractors shall ensure that expenses on administrative costs do not exceed 10% of the total grant.

Administrative expenses may be individually set and may vary; however, the aggregate total of a contractor's administrative costs may not exceed the 10% limit. Administrative activities include:

- usual and recognized overhead activities, including established indirect rates for agencies;
- management oversight of specific programs funded under the RWHAP; and
- other types of program support such as quality assurance, quality control, and related activities (exclusive of RWHAP CQM).

The portion of direct facilities expenses such as rent, maintenance, and utilities for areas primarily utilized to provide core medical and support services for eligible RWHAP clients (e.g., clinic, pharmacy, food bank, counseling rooms, areas dedicated to groups) are not required to be included in the 10% administrative cost cap. Note: by legislation, all indirect expenses must be considered administrative expenses subject to the 10% cap.

For contractors funded by Ryan White Part B, the following programmatic costs are <u>not</u> required to be included in the 10% limit on administrative costs; they may be charged to the relevant service category directly associated with such activities specific to the contract:

- Biannual RWHAP client re-certification;
- The portion of malpractice insurance related to RWHAP clinical care;
- Electronic Medical Records (EMR) data entry costs related to RWHAP clinical care and support services;
- The portion of the clinic receptionist's time providing direct RWHAP patient services (e.g., scheduling appointments and other intake activities);
- The portion of medical waste removal and linen services related to the provision of RWHAP services;
- The portion of medical billing staff related to RWHAP services;
- The portion of a supervisor's time devoted to providing professional oversight and direction regarding RWHAP-funded core medical or support service activities, sufficient to assure the delivery of appropriate and high-quality HIV care, to clinicians, case managers, and other individuals providing services to RWHAP clients (would not include general administrative supervision of these individuals); and
- RWHAP clinical quality management (CQM). However, expenses which are clearly administrative in nature cannot be included as CQM costs.

The following items of expense **are considered administrative** and should be included in the column for administrative costs when completing the budget forms.

(A) Salaries

Management and oversight: This includes staff that has agency management responsibility but no direct involvement in the program or the provision of services.

Finance and Contract administration: This includes proposal, work plan and budget development, receipt and disbursal of contract funds, and preparation of programmatic and financial reports as required by the AIDS Institute.

A position **or** percentage of a position may be considered administrative. Examples of titles that are 100% administrative: Controller, Accounting Manager, Director of Operations, Bookkeeper, Accountant, Payroll Specialist, Finance Coordinator, Maintenance Worker, or Security Officer.

Clinical Guidelines Program Page 35 of 36 Examples of titles that may in part involve administrative duties: Deputy Executive Director; Program Manager, Program Coordinator, or Clinic Manager. With regard to supervision, the percentage of time devoted to supervising programmatic activities and/or providing overall direction to program activities should be considered programmatic.

In the example below, the Chief Operating Officer and Chief Administrative Officer have wholly administrative positions. As such the entire amount requested from the AIDS Institute for these salaries is transferred into the administrative cost line. The Clinic Manager position is 20% administrative so 20% of the requested salary is considered administrative. A calculation on the Salary budget form page will divide all administrative salaries by the total salaries. This percentage in the example below (9.93%) may be applied to items in the miscellaneous category that may be shared by program and administrative staff.

Administrative Cost Updates:

AIRS Data entry staff are **not** required to be included in the 10% limit on Administrative Costs for data entry related to core medical and support services provided to Ryan White HIV/AIDS Program (RWHAP) clients.

Some **examples** based on the recent updates are:

- A Receptionist's time providing direct RWHAP patient services is not required to be counted against the 10% administrative cost limit.
- A Supervisor's time devoted to providing professional oversight and direction regarding RWHAP-funded core medical or support service activities is not required to be included in the 10% administrative cost limit.

Job descriptions provided must describe the position's involvement with these activities in order to justify the charges.

19	1-1	197	177	197	197			jan mino oraniooo oniy
Position Title/Incumbent Name(s) List only those positions funded on this contract. If salary for position will change during the contract period, use additional lines to any salary levels for each period of time. If additional space is needed, copy this page	Hours Worked Per Week Hours worked per week, regardless of funding source.	Annual Salary Salary for 12 months, regardless of funding source.	# of months or pay periods funded on this contract	% of effort worked on this contract	Amount Requested from AIDS Institute <u>Col 3 x Col 4 x Col 5</u> 12 mos. or 26 pp	(1)	Third Party Revenue Show anticipated use of revenue generated by this contract. (Medicaid and ADAP Plus)	Administrative Costs Includes administrative staff salaries supported by this contract. ⁽²⁾
Director of Case Mgt and Treatment Adherence	35	\$65,000	12	75.00%	\$48,750			
Chief Operating Officer	35	\$80,000	12	4.00%	\$3,200			\$3,200
Chief Administrative Officer	35	\$72,000	12	4.00%	\$2,880			\$2,880
Case Manager I	35	\$45,000	12	100.00%	\$45,000			
Clinic Manager	35	\$30,000	12	100.00%	\$30,000			\$6,000
Data Entry	35	\$29,000	12	20.00%	\$5,800			
IT Specialist	35	\$30,000	12	4.00%	\$1,200			\$1,200
SUBTOTAL \$136,830						\$13,280		
Notes:								9.71%

(B) Fringe

The fringe rate should be applied to the amount of staff salaries devoted to administration (\$12,400 in the above example) in order to calculate the amount of administrative fringe benefits. The summary budget form will calculate this amount once the administrative salaries have been identified on the salary page and the fringe rate has been entered on the fringe page.

(C) Supplies

All funds budgeted for office supplies are considered administrative. Supplies such as educational or clinical materials would be considered programmatic. The administrative supply

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amount should be entered directly on the supply budget form.

(D) Travel

Travel pertaining to the financial operations or overall management of the organization is considered administrative. Client travel or travel of program staff to training would be considered programmatic. The administrative travel amount should be entered directly on the travel budget form.

(E) Equipment

Equipment purchased for administrative staff or for the financial operations or overall management of the organization is considered administrative. Equipment purchased for program staff or to support or enhance service delivery would be considered programmatic. The administrative equipment amount should be entered directly on the equipment budget form.

(F) Miscellaneous

Includes any portion of rent, utilities, telecommunications that are not directly related to core medical and support services provided to RWHAP clients. Audit expenses are considered 100% Administrative. Liability insurance can be considered both Administrative and programmatic if a methodology is included by the provider which demonstrates that a portion of the direct service is to RWHAP clients. The percentage of staff time devoted to administration (as calculated on the salary page) should be applied to items of expense shared by program and administrative staff (such as photocopiers, printers, and maintenance agreements).The amount of administrative telecommunications, space and miscellaneous other costs should be entered directly on the miscellaneous budget form.

Cell phone costs for 100% direct program staff will be considered programmatic expenses and should not be charged as administrative costs. If a portion of a staff salary is administrative, then that portion of their cell phone charges must be administrative.

Examples:

- A Case manager has a cell phone whose sole purpose is to use that cell phone for serving Ryan White positive clients would be considered 100% programmatic.
- A Clinic Manager has a cell phone and their administrative effort on the contract is 20%. This means that 20% of the cell phone cost must count towards the 10% administrative cost limit.

(G) Subcontracts/Consultant

Includes contractors who perform non-service delivery functions (bookkeepers, payroll services, accountants, security, maintenance, etc.) The administrative contractual amount should be entered directly on the subcontracts/consultants budget form.

(H) Indirect

100% of funds budgeted in the indirect line are administrative. Any contractor that has never received a Federal negotiated indirect cost rate may charge a de minimis rate of 10% of modified total direct costs. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a contractor chooses to negotiate for a rate, which they may apply to do at any time. The total amount of indirect costs requested should be transferred to the administrative cost line on the indirect costs budget form. **All indirect expenses must be considered administrative expenses subject to the 10% cap.**

The summary budget form will calculate a rate based on the entries made on each budget form. This rate must be 10% or less for Ryan White contractors. We recognize that some administrative resources are

Clinical Guidelines Program Page 37 of 38 needed by contractors to support direct service programs; however, it is important to note that Ryan White funds are meant to support direct services rather than administration. Upon review of the budget, contract managers will work with you if necessary to reduce administrative costs.

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Attachment 3



NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE

HIV · HCV · STIS · SUBSTANCE USE · LGBT HEALTH

Committee Bylaws

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COMMITTEE BYLAWS

A. Guideline Committee Objectives

Guidelines committees are charged with advising the New York State (NYS) Department of Health (DOH) AIDS Institute (AI) on priorities and needs for clinical practice guidelines. The committees work with the AI Contractor in researching, developing, and keeping up-to-date, evidence-based clinical practice guidelines for the care of people living with or at risk of HIV, hepatitis C virus (HCV), sexually transmitted infections (STIs), and substance use , and to promote LGBTQ health in NYS. Committee members also advise the AI on clinical and scientific evidence related to medical care in these areas of practice.

B. Program Requirements

1. Disclosure of Conflicts of Interest

All committee members, contributors, consultants, authors, reviewers (including community advisory committee reviewers), and staff members directly involved in the development of NYSDOH AI clinical guidelines are required to submit a conflict of interest (COI) disclosure annually. COI disclosures must be submitted and reviewed before any work related to the guidelines program commences.

2. Confidentiality Agreement

All committee members, contributors, consultants, authors, reviewers (including community advisory committee reviewers), and staff members directly involved in the development of NYSDOH AI clinical guidelines are required to submit a confidentiality agreement annually. Signed confidentiality agreements must be submitted and reviewed before any work related to the guidelines program commences.

The NYSDOH AI Clinical Guidelines Program relies on the fundamental expectation that all discussion and deliberations undertaken in the development of clinical guidelines are and will remain confidential in nature. Many of the efforts undertaken in the guidelines program involve sensitive issues that may have policy implications. Discussing processes or deliberations, even casually, undermines the confidentiality of the guideline development process and can lead to dire program consequences, including the communication of information that is not accurate or final and the perception that the process is influenced by factors or individuals external unrelated to the program.

To maintain program integrity, the AI requests that each committee member and contributor affirm that he or she understands and agrees to respect the confidential nature of all committee discussions and deliberations, whether conducted in a meeting, on a conference call, by email, or by any other method, and agrees not to share information, discussions, or materials from these meetings with anyone outside of the committee. Sharing of draft documents requires prior written approval of the NYSDOH AI Clinical Guidelines Program.

Failure to comply with these practices will result in dismissal from participation in any guidelines committee supported by the NYSDOH AI Clinical Guidelines Program.

C. Guideline Committee Composition

Members of the clinical guideline committees are practicing clinicians with substantial expertise and experience in the medical care of people who are at risk of acquiring or who are living with HIV, HCV, STIs, and substance use and associated comorbidities in NYS.

Other members include the AI Contracting Medical Lead; public health liaisons appointed by the AI Medical Director; and community stakeholders.

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1. Committee Size, Diversity, and Makeup

Each committee will have no fewer than 8 and no more than 25 members. Up to 70% of committee members may practice in/represent New York City (NYC). At least 30% of committee members must represent areas of NYS beyond NYC. To the degree possible, committee members should represent the array of practice settings in which care is delivered to people living with HIV, HCV, STIs, and substance use throughout the state and should represent the gender, race, and ethnic diversity of patient populations throughout NYS as well.

NYSDOH AI Clinical Liaison: The Medical Director will appoint a medical staff person from the AI Office of the Medical Director to be a clinical liaison to the Medical Care Criteria Committee (MCCC) and this liaison will be available to other committees as needed. This appointment will be reviewed every 2 years by the Medical Director.

The AI Clinical Liaison will participate in all MCCC calls and meetings, providing clinical guidance and input from an AI perspective. The NYSDOH AI Clinical Liaison will not vote on committee issues or recommendations.

New members: When a committee vacancy arises, any member of the committee may suggest candidates to fill that vacancy. New members will be invited to participate after 1) the AI has determined no prohibited conflicts of interest exist; and 2) consideration is given to perspectives currently represented on the committee in an effort to ensure member diversity.

It is the prerogative of the Medical Director (or designee) to appoint new members to any committee at any time and to request at any time that a committee member step down.

Constitution of a new committee: At any time, the AI may identify the need for a new committee to address an emerging need in patient care. Appointment of committee members is at the discretion of the AI upon review and approval of credentials and COI disclosures of potential members. A new committee's work will commence with an in-person meeting facilitated by the AI and AI Contractor to articulate the purpose and goals of the committee and establish plans for accomplishing those goals.

2. Leadership

Each clinical guideline committee will have a chair and a vice-chair appointed by the AI Medical Director or designee. The AI will assign a clinical liaison or a program liaison to participate in each committee as a member of the committee's planning group.

Chair: Each committee will have a chair, named by the AI Medical Director, who will serve a 2-year term. A chair's term may be extended for up to 2 years by request of the AI and agreement of the chair and vice-chair. Once a chair's term is ended, the former chair will be invited to serve as chair emeritus for 2 years, a term that may be extended at the discretion of the AI in consultation with committee leadership.

The chair's responsibilities include, but may not be limited to, the following:

- Working with the AI, committee members, and AI Contractor to identify priorities for new guideline development and updates.
- Identifying authors and peer reviewers for guidelines and updates.
- Providing expert input during guideline development and review, which may include reviewing the literature, evaluating evidence, comparing with other guidelines, reviewing and editing manuscripts, consulting with subject matter experts who are external to the committee, and providing feedback on authors' work.
- Steering the discussions of the planning group and committee during document review and ratings; negotiating agreement among all parties when there is controversy.
- Authoring guidelines and updates.
- Conducting final review and approving guideline manuscripts before submission to the AI.
- Reviewing and leading management of declared COIs among committee members.
- Evaluating and approving the credentials and suitability of experts nominated for committee membership.
- Leading the discussion during in-person committee meetings.
- Making recommendations regarding ongoing participation of committee members, as needed.
- Participating in the NYSDOH AI Clinical Guidelines Program's Steering Committee.
- Serving as chair emeritus for at least 2 years after completion of tenure as chair.

Clinical Guidelines Program Page 41 of 42 · Consulting with and advising the AI as needed on matters pertinent to the guidelines.

Vice-Chair: Each committee will have a vice-chair, named by the AI Medical Director, who will serve a 2-year term. A vice-chair's term may be extended for up to 2 years by request of the AI and agreement of the chair and vice-chair. Once the term is ended, the former vice-chair will be asked to serve as chair for at least 2 years, a term that can be extended at the discretion of the AI.

- Assisting the chair with committee management and guideline development as needed.
- Authoring guidelines and updates.
- Serving as chair for at least 2 years after completion of tenure as vice-chair.
- Stepping in as committee chair if the designated chair is unable to complete his/her term.

Chair Emeritus: The primary role of the Chair Emeritus is to ensure continuity of committee operations and to advise the planning group on procedural and clinical issues. The Chair Emeritus is a member of the committee planning group and may fully participate in all committee activities. The Chair Emeritus may author guidelines, participates in all planning group reviews of guidelines, and may be asked to rate recommendations when appropriate, given knowledge of the subject matter and published literature. The tenure of the Chair Emeritus is 2 years.

AIDS Institute Medical Director: The AI Medical Director identifies and invites new committee members, oversees the development of all guidelines and grants final approval for the entire content (including all recommendations, rationale, evidence, key points, tables/graphics, and appendices) and publication of all guidelines.

The Medical Director holds final decision-making authority in any instance of contested content and/or methods, policies or procedures for all guidelines, collateral materials, and the <u>www.hivguidelines.org</u> website. These final approvals and decisions are based on AI priorities, professional clinical expertise, and suggestions from the guidelines committee(s) and program staff.

Director, AI Contractor for the Clinical Guidelines Program: The AI Contractor Director advises committees on procedural and clinical issues. This person does not author guidelines but is invited to participate in all planning group reviews of guidelines, all deliberations on recommendations, and all committee discussions of recommendations specifically and guidelines in general. This person may be asked to rate recommendations when appropriate, given their knowledge of the subject matter and published literature.

Planning group: Each committee will have a designated planning group (or planning subcommittee) comprising the chair, vice-chair, chair emeritus (if available), AI clinical or program liaison, AI Contractor Principal Investigator, and a representative from a community organization designated by the AI OMD. Other committee members may be invited to join a committee's planning group at the discretion of the chair or the AI. When guidelines are published, the planning group members are listed in the guideline's byline as "Writing Group" members.

When a specific guideline is being reviewed at any time during development, the lead author may be invited to participate in the planning group discussion. Other planning group participants include the NYSDOH AI Clinical Guidelines Program Manager and AI Contractor editorial staff. The Medical Director or designee will be invited to and may participate in any or all planning group meetings.

The role of the planning group is to provide the first line of review, feedback, and revision through all stages of guideline development. The planning group works with a guideline lead author in developing the outline and draft recommendations, reviews the literature, and participates in rating of recommendations and discussions held during full committee review.

The MCCC planning group meets monthly during a standing conference call to discuss committee plans, review documents, and address other committee-related business. The planning groups of other committees meet as needed, with calls scheduled at the frequency required to maintain momentum on a specific project.

Invited planning group participants and/or expert consultants: At any time, committee leaders, other planning group members, an author, or the AI may invite members of other guidelines committees or external consultants/subject matter experts to participate in planning group activities related to the review, update, or development of a specific guideline. Participation will end once a guideline has been approved by the AI and published.

Clinical Guidelines Program Page 42 of 43 **Program steering committee:** The purpose of the program steering committee is to review the program's current offerings and priorities, plan responses to emerging needs, and identify future efforts. The program steering committee meets at least annually. Members include the AI Medical Director, the AI Contractor Director; chairs, vice-chairs, and chairs emeritus (if available) from each active committee; Clinical Guidelines Program staff and editors; and other relevant content experts as deemed appropriate by the AI Medical Director.

3. Terms of Service

Committees: Upon election or appointment to a guidelines committee, members will be asked to agree to serve a 4-year term, with the option to continue participation via annual consent to extend the term. The agreement to extend committee membership will be requested along with a disclosure of COIs and a confidentiality agreement in January of each calendar year. There is no maximum term of committee membership.

If a committee member is not meeting the responsibilities of membership, then the committee leaders, in consultation with the AI, may approach the member and ask him/her to step down.

When a contributing member vacates a seat on a guidelines committee, the remaining members will be invited to suggest a replacement for consideration by the AI. The AI will make the final decision about committee member invitations or appointments.

Chairs and vice-chairs: The Medical Director appoints the chair and vice-chair for each committee. Chairs and vicechairs are asked to commit to a 2-year term that may be extended at the discretion of the OMD, with agreement of the chair and vice-chair. Upon completion of a chair's term, the vice-chair is invited by the OMD to serve as chair, and the retiring chair will be invited to serve as chair emeritus for 2 years. The decision to invite a vice-chair to assume the chair of a committee rests with the OMD. The decision to continue as chair emeritus rests with the committee member and committee chairs.

- Liaisons: The AI requests the agency/organization to be represented on a guidelines committee to identify an
 individual to serve as a liaison for 2 years. At the end of this term, the AI and the liaison's organization will
 determine whether the same individual is available to serve another term or whether another individual
 should be appointed.
- Community Advisers: The AI invites at least one member of at least 1 community organization to serve as a liaison for 2 years. At the end of this term, the AI and the organization will determine whether the same individual is available to serve another term or whether another individual should be appointed.
- Consultants/Subject Matter Experts: Terms are restricted to the period of development of a specific guideline at the discretion of committee leadership.
- AI Clinical and Program Liaisons: The AI will identify individuals to serve as liaisons for 2 years. At the end of
 this term, OMD and appropriate program staff will determine whether the same individual is available to serve
 another term or whether another individual should be appointed.
- Consumers: The AI will identify individuals to serve as consumer reviewers for 1 year. At the end of this term, OMD and appropriate program staff will determine whether the same individual is available to serve another term or whether another individual should be appointed.

D. Committee Responsibilities and Decision-Making

Committees are responsible for identifying the need for and participating in the development of clinical practice guidelines identified by the AI to meet the needs of clinical practitioners and patients in NYS.

1, Recommendations and Guideline Text

Adoption of new recommendations or changes in existing recommendations and/or substantive changes to the body of a guideline must be reviewed and accepted by the full committee, with a 2/3 majority constituting acceptance.

Clinical Guidelines Program Page 43 of 44 New guidelines must be approved by 2/3 of the committee. All members of a committee (leadership, contributing members, liaisons, community stakeholders, and public health liaisons) will be asked to review and comment on draft manuscripts at several points during development.

Evaluation of evidence and rating of recommendations: Approved recommendations and the supporting evidence will be reviewed and rated by at least four members of a committee, including the Chair, Vice-Chair, lead author, and one other recommended by the Chair or the lead author. Chairs may decide to add additional raters or may approve a smaller number of raters if appropriate. Planning group members who are not rating the recommendations of a guideline may participate in the discussion of ratings. Upon full committee review of draft recommendations, the ratings given to the recommendations may be questioned and changed with the concurrence of the raters.

2. Nomination of Candidates for Committee Membership

All committee members may nominate candidates for committee membership when another member's term ends for any reason. The Medical Director must approve all committee members.

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ATTACHMENT 4 –WORK PLAN SUMMARY

PROJECT NAME: AIDS Institute Clinical Guidelines Program

CONTRACTOR SFS PAYEE NAME:

CONTRACT PERIOD: From: July 1, 2022

To: June 30, 2027

A fully qualified contracting agency will provide a wide range of professional processes and administrative activities associated with the following phases of clinician guidelines to address the medical management and treatment needs of individuals with or at risk of HIV infection, viral hepatitis (HCV), sexually transmitted infections (STIs), and drug user and LGBTQ health:

- 1. <u>Development and Maintenance</u>: Guidelines committee membership, the workflow of each committee, support of the authors and reviewers, contact with committee chairs and members as well as guidelines conference calls and meetings, are arranged by the contractor. Professional editing, content design, and formatting of the clinical guidelines is provided by the contractor.
- 2. <u>Dissemination</u>: Ensure that the guideline content on www.hivguidelines.org is published in a user-friendly, mobile-friendly format which is visually engaging and up to date. Identify mechanisms to increase the visibility, accessibility, and credibility of the clinical guidelines. Maintain routine mass communications to guideline users.
- 3. <u>Implementation</u>: Host and participate in routine collaborative meetings with programmatic partners to foster the implementation of the AI clinical guidelines.
- 4. <u>Evaluation</u>: Gather feedback from clinicians and/or professional clinical societies in New York State (NYS) on their use and views of the New York State Department of Health AIDS Institute (NYSDOH AI) clinical guidelines; utilize data to evaluate success of the program.

Instructions: For the Grants Gateway Work Plan Project Summary, applicants are instructed to insert the Project Summary as it is listed above. In the Grants Gateway Work Plan Organizational Capacity section, applicants are instructed to list this as "not applicable." Any additional Project Summary or Organizational Capacity entered in these areas will not be considered or scored by reviewers of your application.

Funded applicants will be held to the Objective, Tasks, and Performance Measures as listed in Attachment 4: Work Plan. Applicants are <u>not</u> required to enter any Objectives, Tasks or Performance Measures into the Grants Gateway Work Plan.

ATTACHMENT 4 –WORK PLAN DETAIL

OBJECTIVE	TASKS	PERFORMANCE MEASURES
1: Develop new clinical guidelines relevant to the NYSDOHAI topic areas.	1.1 Develop, propose, obtain NYSDOH AI approval of, and implement a methodology for the development of trustworthy clinical guidelines.	1.1.1 A NYSDOH AI-approved detailed methodology is documented and utilized to guide and report on the development of all clinical guidelines and related materials.
	1.2 Manage guideline committee, consumer review, and peer review workflow.	1.2.1 Committee conference calls to review evidence, rate recommendations, are held and documented.
		1.2.2 Feedback from peer and consumer reviewers is documented and communicated to the author(s), committee, and NYSDOH AI leadership as appropriate.
	1.3 Ensure provision of trustworthy evidence.	1.3.1 An evidence table based on a systematic literature search is documented and made available for program participants, staff, and leadership for each guideline in development.
	1.4 Provide professional editing, content design, and formatting.	1.4.1 Acceptance of guideline manuscript by AI program leadership.
	1.5 Ensure medical editorial staff keep abreast of developments in the field of HIV, HCV, STIs, substance use, and LGBTQ health and these developments are reflected in guidelines documents.	1.5.1 Staff attendance at relevant trainings and conferences is documented annually and as appropriate.
	1.6 Manage multiple manuscript development processes simultaneously.	1.6.1 Monthly status reports are submitted in a timely and completed fashion.

OBJECTIVE	TASKS	PERFORMANCE MEASURES
	1.7 Ensure fidelity across existing related guidelines as new guidelines are developed.	1.7.1 Scanning results of all guideline content and needed changes to ensure fidelity is documented and reported to the NYSDOH AI.
	1.8 Related administrative and operational activities.	1.8.1 Evidence of completion of tasks is documented and reported to the NYSDOH AI monthly.
2: Ensure that existing guidelines are kept up to date.	2.1 Develop, propose, obtain NYSDOH AI approval of, and implement a methodology for the updating of trustworthy clinical guidelines.	2.1.1 ANYSDOH AI-approved detailed methodology is documented and utilized to guide and report on the updating of all clinical guidelines and related materials.
	2.2 Develop and utilize system to track guideline inventory and routinely update all guidelines 3 or more years old.	2.2.1 Guideline review is documented; publication review date indicated and made publicly available.
	2.3 Provide professional editing. content design, and formatting.	2.3.1 Acceptance of guideline manuscript by AI program leadership.
	2.4 Related administrative and operational activities.	2.4.1 Evidence of completion of tasks is documented and reported to the NYSDOH AI monthly.
3: Widely disseminate guideline content to clinical audiences in NYS & beyond.	3.1 Manage and enhance www.hivguidelines.org.	3.1.1 Website design and function is approved by AI program leadership.
	3.2 Identify and implement methods to grow the program's social media presence.	3.2.1 Social media data is provided to the NYSDOH AI via routine reports.
	3.3 Maintain monthly newsletter creation each month, expand audience.	3.3.1 Monthly newsletter is published and disseminated.
	3.4 Submit newly created/recently updated guidelines to the National Library of Medicine (NLM) Literature Archive as they are published.	3.4.1 NYSDOH AI guidelines are searchable and identifiable in NLM Literature Archive database.

OBJECTIVE	TASKS	PERFORMANCE MEASURES
	3.5 Explore additional mechanisms of dissemination, including podcasts and complimentary materials with each newly created and updated guideline.	3.5.1 Report proposed plan to NYSDOH AI program leadership.
	3.6 Related administrative and operational activities.	3.6.1 Evidence of completion of tasks is documented and reported to the NYSDOH AI monthly.
4: Foster implementation of NYSDOH AI guidelines.	4.1 Host and participate in collaborative meetings.	4.1.1 Participation in meetings is documented, action steps identified in these meetings are demonstrably completed and reported to NYSDOH AI program leadership monthly.
	4.2 Conducting research and feasibility studies exploring CME as a mechanism to aid implementation of the guidelines.	4.2.1 Report findings and proposed plan to NYSDOH AI program leadership within year 1 of 5-year award.
	4.3 Related administrative and operational activities.	4.3.1 Evidence of completion of tasks is documented and reported to the NYSDOH AI monthly.
5: Evaluate Guidelines usage.	5.1 Obtain feedback from clinicians and/or professional clinical societies in NYS on their use and views of the	5.1.1 Propose evaluation plan to NYSDOH AI program leadership annually.
	NYSDOH AI clinical guidelines.	5.1.2 Report findings annually within 2 months of end of contract year.
	5.2 Related administrative and operational activities.	5.2.1 Evidence of completion of tasks is documented and reported to the NYSDOH AI monthly.
6: Evaluate performance of the program.	6.1 Analyze and report website utilization and citation tracking data to evaluate success quarterly.	6.1.1 Policies and procedures are in place to review and discuss evaluation results with the NYSDOH AI.

OBJECTIVE	TASKS	PERFORMANCE MEASURES
		6.1.2 Evaluation results are used to improve future program activities.
	6.2 Related administrative and operational activities.	6.2.1 Evidence of completion of tasks is documented and reported to the NYSDOH AI monthly.
7. Flexibility in programming for directing resources effectively.	7.1 Flexibility in programming is necessary to ensure that resources are effectively directed to projects that meet the needs of both the NYSDOH AI and the users of the guidelines.	7.1.1 N/A
	7.2 Contract activities & deliverables may be modified at any point in this contract upon direction of the NYSDOH AI to address emerging needs.	7.2.1 Aid with non-workplan issues if/when they arise.

Attachment 5 General Terms and Conditions - Health Research Incorporated Contracts

 Term - This Agreement shall be effective and allowable costs may be incurred by the Contractor from the Contract Start Date through the Contract End Date, (hereinafter, the "Term") unless terminated sooner as hereinafter provided or extended by mutual agreement of the parties.

2. Allowable Costs/Contract Amount -

- a) In consideration of the Contractor's performance under this Agreement, HRI shall reimburse the Contractor for allowable costs incurred in performing the Scope of Work, which is attached hereto as Exhibit A, in accordance with the terms and subject to the limits of this Agreement.
- b) It is expressly understood and agreed that the aggregate of all allowable costs under the Agreement shall in no event exceed the Total Contract Amount, except upon formal amendment of this Agreement as provided herein below.
- c) The allowable cost of performing the work under this Agreement shall be the costs approved in the Budget attached hereto as Exhibit B and actually incurred by the Contractor, either directly incident or properly allocable, to the Agreement, in the performance of the Scope of Work. For work performed under a Scope of Work that results from a federally funded grant or contract, Contractor's costs must be in accordance with cost principles of the Department of Health and Human Services Grants Policy Statement (HHS GPS). To be allowable, a cost must be reasonable, necessary, and cost-effective (as reasonably determined by HRI). In calculating costs, the accounting practices of Contractor must be based on generally accepted accounting principles and practices appropriate to the circumstances and consistent with other comparable activities of Contractor. Costs resulting from inconsistent practices in excess of the amount that would have resulted from using practices consistent with this Section 2(c) are unallowable. Contractor shall supply documentation of such policies and procedures to HRI when requested.
- d) Irrespective of whether the "Audit Requirements" specified in paragraph 3(a) are applicable to this Agreement, all accounts and records of cost relating to this Agreement shall be subject to audit by HRI or its duly authorized representative(s) and/or the Project Sponsor during the Term and for three years after the final voucher is submitted for payment. This provision includes the right for HRI to request copies of source documentation in support of any costs claimed. If an audit is started before the expiration of the 3-year period, the records must be retained until all findings involving the records have been resolved and final action taken. Any reimbursement made by HRI under this Agreement shall be subject to retroactive correction and adjustment upon such audits. The Contractor agrees to repay HRI promptly any amount(s) determined on audit to have been incorrectly paid. HRI retains the right, to the extent not prohibited by law or its agreements with the applicable Project Sponsor(s) to recoup any amounts required to be repaid by the Contractor to HRI by offsetting those amounts against amounts due to the Contractor from HRI pursuant to this or other agreements. The Contractor shall maintain appropriate and complete accounts, records, documents, and other evidence showing the support for all costs incurred under this Agreement.

3. Administrative, Financial and Audit Regulations -

a) This Agreement shall be audited, administered, and allowable costs shall be determined in accordance with the terms of this Agreement and the requirements and principles applicable to the Contractor as noted below, including, but not limited to, the Office of Management and Budget (OMB) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (referred to herein as the "Uniform Guidance") as codified in Title 2 of the Code of Federal Regulations. The federal regulations specified below apply to the Contractor (excepting the "Audit Requirements," which apply to federally- funded projects only), regardless of the source of the funding specified (federal/non-federal) on the face page of this Agreement. For non-federally funded projects any right granted by the regulation to the federal sponsor shall be deemed granted to the Project Sponsor. It is understood that a Project Sponsor may impose restrictions/requirements beyond those noted below in which case such restrictions/requirements will be noted in Attachment B Program Specific Clauses.

Contractor Type	Administrative Requirements	Cost Principles	Audit Requirements Federally Funded Only
College or University	Uniform Guidance	Uniform Guidance	Uniform Guidance
Not-for-Profit	Uniform Guidance	Uniform Guidance	Uniform Guidance
State, Local Gov. or Indian Tribe	Uniform Guidance	Uniform Guidance	Uniform Guidance
For-Profit	45 CFR Part 74	48 CFR Part 31.2	Uniform Guidance
Hospitals	2 CFR Part 215	45 CFR Part 74	Uniform Guidance

Clinical Guidelines Program Page 50 of 51 b) If this Agreement is federally funded, the Contractor will provide copies of audit reports required under any of the above audit requirements to HRI within 30 days after completion of the audit.

4. Payments -

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

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

- b) The Contractor shall submit voucher claims and reports of expenditures at the Required Voucher Frequency noted on the face page of this Agreement, in such form and manner, as HRI shall require. HRI will reimburse Contractor upon receipt of expense vouchers pursuant to the Budget in Exhibit B, so long as Contractor has adhered to all the terms of this Agreement and provided the reimbursement is not disallowed or disallowable under the terms of this Agreement. All information required on the voucher must be provided or HRI may pay or disallow the costs at its discretion. HRI reserves the right to request additional back up documentation on any voucher submitted. Further, all vouchers must be received within thirty (30) days of the end of each period defined as the Required Voucher Frequency (i.e. each month, each quarter). Contractor shall submit a final voucher designated by the Contractor as the "Completion Voucher" no later than sixty (60) days from termination of the Agreement. Vouchers received after the 60 day period may be paid or disallowed at the discretion of HRI.
- c) The Contractor agrees that if it shall receive or accrue any refunds, rebates, credits or other amounts (including any interest thereon) that relate to costs for which the Contractor has been reimbursed by HRI under this Agreement it shall notify HRI of that fact and shall pay or, where appropriate, credit HRI those amounts.
- d) The Contractor represents, warrants and certifies that reimbursement claimed by the Contractor under this Agreement shall not duplicate reimbursement received from other sources, including, but not limited to client fees, private insurance, public donations, grants, legislative funding from units of government, or any other source. The terms of this paragraph shall be deemed continuing representations upon which HRI has relied in entering into and which are the essences of its agreements herein.
- 5. Termination Either party may terminate this Agreement with or without cause at any time by giving thirty (30) days written notice to the other party. HRI may terminate this Agreement immediately upon written notice to the Contractor in the event of a material breach of this Agreement by the Contractor. It is understood and agreed, however, that in the event that Contractor is in default upon any of its obligations hereunder at the time of any termination, such right of termination shall be in addition to any other rights or remedies which HRI may have against Contractor by reason of such default. Upon termination of the Agreement by either party for any reason, Contractor shall immediately turn over to HRI any works in progress, materials, and deliverables (whether completed or not) related to the services performed up to the date of termination.
- 6. Representations and Warranties Contractor represents and warrants that:
 - a) it has the full right and authority to enter into and perform under this Agreement;
 - b) it will perform the services set forth in Exhibit A in a workmanlike manner consistent with applicable industry practices;
 - c) the services, work products, and deliverables provided by Contractor will conform to the specifications in Exhibit A;
 - d) there is no pending or threatened claim or litigation that would have a material adverse impact on its ability to perform as required by this Agreement.

Clinical Guidelines Program Page 51 of 52 7. Indemnity - To the fullest extent permitted by law, Contractor shall indemnify, hold harmless and defend HRI, its agents, employees, officers, board members, the New York State Department of Health, and the People of the State of New York against all claims, damages, losses or expenses including but not limited to attorneys' fees arising out of or resulting from the performance of the agreement, provided any such claim, damage, loss or expense arises out of, or in connection with, any act or omission by Contractor, or anyone directly or indirectly employed or contracted by Contractor, in the performance of services under this Agreement, and such acts or omissions (i) constitute negligence, willful misconduct, or fraud; (ii) are attributable to bodily injury, sickness, disease or death, or to injury to or destruction of tangible property, including loss of use resulting there from; (iii) cause the breach of any confidentiality obligations set forth herein; (iv) relate to any claim for compensation and payment by any employee or agent of Contractor; (v) result in intellectual property infringement or misappropriation by Contractor, its employees, agents, or subcontractors; or (vi) are violations of regulatory or statutory provisions of the New York State Labor Law, OSHA or other governing rule or applicable law. The obligation of the Contractor to indemnify any party under this paragraph shall not be limited in any manner by any limitation of the amount of insurance coverage or benefits including workers' compensation or other employee benefit acts provided by the Contractor. In all subcontracts entered into by the Contractor related to performance under this Agreement, the Contractor will include a provision requiring the subcontractor to provide the same indemnity and hold harmless to the indemnified parties specified in this paragraph.

8. Amendments/Budget Changes -

- a) This Agreement may be changed, amended, modified or extended only by mutual consent of the parties provided that such consent shall be in writing and executed by the parties hereto prior to the time such change shall take effect, with the exception of changes and amendments that are made mandatory by the Project Sponsor under the sponsoring grant/contract, which will take effect in accordance with the Project Sponsor's requirements and schedule.
- b) In no event shall there be expenses charged to a restricted budget category without prior written consent of HRI.
- c) The Budget Flexibility Percentage indicates the percent change allowable in each category of the Budget, with the exception of a restricted budget category. As with any desired change to this Agreement, budget category deviations exceeding the Budget Flexibility Percentage in any category of the Budget are not permitted unless approved in writing by HRI. In no way shall the Budget Flexibility Percentage be construed to allow the Contractor to exceed the Total Contract Amount less the restricted budget line, nor shall it be construed to permit charging of any unallowable expense to any budget category. An otherwise allowable charge is disallowed if the charge amount plus any Budget Flexibility Percentage exceeds the amount of the budget category for that cost.

9. Insurance -

- a) The Contractor shall maintain or cause to be maintained, throughout the Term, insurance or self-insurance equivalents of the types and in the amounts specified in section b) below. Certificates of Insurance shall evidence all such insurance. It is expressly understood that the coverage's and limits referred to herein shall not in any way limit the liability of the Contractor. The Contractor shall include a provision in all subcontracts requiring the subcontractor to maintain the same types and amounts of insurance specified in b) below.
- b) The Contractor shall purchase and maintain at a minimum the following types of insurance coverage and limits of liability:
 - 1) Commercial General Liability (CGL) with limits of insurance of not less than \$1,000,000 each Occurrence and \$2,000,000 Annual Aggregate. If the CGL coverage contains a General Aggregate Limit, such General Aggregate shall apply separately to each project. HRI and the People of the State of New York shall be included as Additional Insureds on the Contractor's CGL, using ISO Additional Insured Endorsement CG 20 10 11 85 or an endorsement providing equivalent coverage to the Additional Insureds. The CGL insurance for the Additional Insureds shall be as broad as the coverage provided for the Named Insured Contractor. It shall apply as primary and non-contributing insurance before any insurance maintained by the Additional Insureds.
 - Business Automobile Liability (AL) with limits of insurance of not less than \$1,000,000 each accident. AL
 coverage must include coverage for liability arising out of all owned, leased, hired and non-owned automobiles.
 - Workers Compensation (WC) & Employers Liability (EL) with limits of insurance of not less than \$100,000 each accident for bodily injury by accident and \$100,000 each employee for injury by disease.
 - If specified by HRI, Professional Liability Insurance with limits of liability of \$1,000,000 each occurrence and \$3,000,000 aggregate.
- c) Provide that such policy may not be canceled or modified until at least 30 days after receipt by HRI of written notice thereof; and

Clinical Guidelines Program Page 52 of 53 d) Be reasonably satisfactory to HRI in all other respects.

10. Publications and Conferences -

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

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

11. Title -

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

12. Confidentiality - Information relating to individuals who may receive services pursuant to this Agreement shall be maintained and used only for the purposes intended under the Agreement and in conformity with applicable provisions of laws and regulations or specified in Attachment B, Program Specific Clauses. Contractor acknowledges and agrees that, during the course of performing services under this Agreement, it may receive information of a confidential nature, whether marked or unmarked, ("Confidential Information"). Contractor agrees to protect such Confidential Information with the same degree of care it uses to protect its own confidential information of a similar nature and importance, but with no less than reasonable care. Contractor will not use Confidential Information for any purpose other than to facilitate the provision of services under this Agreement, and Contractor will not disclose Confidential Information in an unauthorized manner to any third party without HRI's advance written consent.

13. Equal Opportunity and Non-Discrimination - Contractor acknowledges and agrees, whether or not required by Article 15 of the New York State Executive Law (also known as the Human Rights Law) or any other State or Federal statutory or constitutional non-discrimination provisions, that Contractor will not discriminate against any employee or applicant for employment because of race, color, creed, religion, sex, sexual orientation, gender identity, national origin, age, disability, pregnancy-related condition, military or veteran status, genetic predisposition or carrier status, marital or familial status, domestic violence victim status, individual's relationship or association with a member of a protected category or any other basis protected by applicable state and federal law. Furthermore, Contractor agrees that neither it nor its authorized subcontractors, if any, shall, by reason of race, color, creed, religion, sex, sexual orientation, gender identity, national origin, age, disability, pregnancy-related condition, military or veteran status, genetic predisposition or carrier status, marital or familial origin, age, disability, pregnancy-related condition, military or veteran status, genetic predisposition or carrier status, marital or

Clinical Guidelines Program Page 53 of 54 familiar status, domestic violence victim status, individual's relationship or association with a member of a protected category or any other basis protected by applicable state and federal law: (a)discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the performance of work under this Agreement. Contractor is subject to fines of \$50.00 per person per day for any violation of this provision, or of Section 220-e or Section 239 of the New York State Labor Law, as well as possible termination of this Agreement and forfeiture of all moneys due hereunder for a second or subsequent violation.

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

15. Site Visits and Reporting Requirements -

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

16. Miscellaneous -

- a) Contractor and any subcontractors are independent contractors, not partners, joint venturers, or agents of HRI, the New York State Department of Health or the Project Sponsor; nor are the Contractor's or subcontractor's employees considered employees of HRI, the New York State Department of Health or the Project Sponsor for any reason. Contractor shall pay employee compensation, fringe benefits, disability benefits, workers compensation and/or withholding and other applicable taxes (collectively the "Employers Obligations") when due. The contractor shall include in all subcontracts a provisions requiring the subcontractor to pay its Employer Obligations when due. Contractor is fully responsible for the performance of any independent contractors or subcontractors.
- b) This Agreement may not be assigned by the Contractor or its right, title or interest therein assigned, transferred, conveyed, sublet, subjected to any security interest or encumbrance of any type, or disposed of without the previous consent, in writing, of HRI.
- c) This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.
- d) Contractor shall have no interest, financial or otherwise, direct or indirect, or engage in any business, transaction, or professional activity, that may create a conflict, or the appearance of a conflict, with the proper discharge of Contractor's duties under this Agreement or the conflict of interest policy of any agency providing federal funding under this Agreement. In the event any actual or potential conflict arises, Contractor agrees to notify HRI in writing within ten (10) days to allow HRI to evaluate any potential or actual conflict. Contractor certifies that it has implemented and is in compliance with a financial conflict of interest policy that complies with 42 CFR Part 50 Subpart F, as may be amended from time to time. Contractor acknowledges that it cannot engage in any work or receive funding from HRI until they have disclosed all financial conflicts of interest and identified an acceptable management strategy to HRI. At HRI's request, Contractor will provide information about how it identified, managed, reduced or eliminated conflicts of interest. Failure to disclose such conflicts or to provide information to HRI may be cause for termination as specified in the Terms & Conditions of this Agreement. HRI shall provide Contractor with a copy of notifications sent to the funding agency under this Agreement.
- e) Regardless of the place of physical execution or performance, this Agreement shall be construed according to the laws of the State of New York and shall be deemed to have been executed in the State of New York. Any action to enforce, arising out of or relating in any way to any of the provisions of this Agreement may only be brought and prosecuted in such court or courts located in the State of New York as provided by law; and the parties' consent to the jurisdiction of said court or courts located in the State of New York and to venue in and for the County of Albany to the exclusion of all other court(s) and to service of process by certified or registered mail, postage prepaid, return

Clinical Guidelines Program Page 54 of 55 receipt requested, or by any other manner provided by law. The provisions of this paragraph shall survive the termination of this Agreement.

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

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

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

- a) Human Subjects, Derived Materials or Data If human subjects are used in the conduct of the work supported by this Agreement, the Contractor agrees to comply with the applicable federal laws, regulations, and policy statements issued by DHHS in effect at the time the work is conducted, including by not limited to Section 474(a) of the HHS Act, implemented by 45 CFR Part 46 as amended or updated. The Contractor further agrees to complete an OMB No. 0990-0263 form on an annual basis.
- b) Laboratory Animals If vertebrate animals are used in the conduct of the work supported by this Agreement, the Contractor shall comply with the Laboratory Animal Welfare Act of 1966, as amended (7 USC 2131 et. seq.) and the regulations promulgated thereunder by the Secretary of Agriculture pertaining to the care, handling and treatment of vertebrate animals held or used in research supported by Federal funds. The Contractor will comply with the HHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.
- c) Research Involving Recombinant DNA Molecules The Contractor and its respective principle investigators or research administrators must comply with the most recent *Public Health Service Guidelines for Research Involving Recombinant DNA Molecules* published at Federal Register 46266 or such later revision of those guidelines as may be published in the Federal Register as well as current *NIH Guidelines for Research Involving Recombinant DNA Molecules*.
- d) Contractor is required to register with SAM.gov and maintain active status as stated in 2 CFR Subtitle A, Chapter 1, and Part 25. Contractor must maintain the accuracy/currency of the information in SAM at all times during which the Contractor has an active agreement with HRI. Additionally, the Contractor is required to review and update the information at least annually after the initial registration, and more frequently if required by changes in information.
- e) Equal Employment Opportunity for all agreements

Clinical Guidelines Program Page 55 of 56 This contractor and subcontractor shall abide by the requirements of 41 CFR 60-1.4(a) which is hereby incorporated herein.

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

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

f) National Labor Relations Act (Executive Order 13496)

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

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

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

- a) If the Project Sponsor is an agency of the Department of Health and Human Services: The Contractor must be in compliance with the following Department of Health and Human Services and Public Health Service regulations implementing the statutes referenced below and assures that, where applicable, it has a valid assurance (HHS-690) concerning the following on file with the Office of Civil Rights, Office of the Secretary, HHS.
 - 1) Title VI of the Civil Rights Act of 1964 as implemented in 45 CFR Part 80.
 - 2) Section 504 of the Rehabilitation Act of 1973, as amended, as implemented by 45 CFR Part 84.
 - 3) The Age Discrimination Act of 1975 (P.L. 94-135) as amended, as implemented by 45 CFR 1.
 - Title IX of the Education Amendments of 1972, in particular section 901 as implemented at 45 CFR Part 86 (elimination of sex discrimination).
 - Sections 522 and 526 of the HHS Act as amended, implemented at 45 CFR Part 84 (non-discrimination for drug/alcohol abusers in admission or treatment).
 - Section 543 of the HHS Act as amended as implemented at 42 CFR Part 2 (confidentiality of records of substance abuse patients).
 - Trafficking in Persons subject to the requirement of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104).
 - HHS regulatory requirements on Responsibility of Applicants for Promoting Objectivity in Research and financial conflicts of interest set forth in 42 C.F.R Parts 50 and 94.
 - Contractor agrees to comply with other requirements of the Project Sponsor, if applicable, set forth in the HHS Grants Policy Statement.
- b) Notice as Required Under Public Law 103-333: If the Project Sponsor is an agency of the Department of Health and Human Services, the Contractor is hereby notified of the following statement made by the Congress at Section 507(a) of Public Law 103-333 (The DHHS Appropriations Act, 1995, hereinafter the "Act"): It is the sense of the Congress that, to the greatest extent practicable, all equipment and products purchased with funds made available in this Act should be American-made.
- c) Contractor agrees that if the Project Sponsor is other than an agency of the DHHS, items 1, 2, 3 and 4 in subsection a) above shall be complied with as implemented by the Project Sponsor.
- d) Contractor agrees that the Standard Patent Rights Clauses under the Bayh-Dole Act (37 C.F.R 401) are hereby incorporated by reference and shall supersede any terms in this Agreement that may conflict therewith.
- e) Criminal Penalties for Acts Involving Federal Health Care Programs Recipients and sub-recipients of Federal funds are subject to the strictures of 42 U.S.C. 1320A-7B(b)) and should be cognizant of the risk of criminal and administrative liability under this statute, including for making false statements and representations and illegal remunerations.
- Equipment and Products To the greatest extent practicable, all equipment and products purchased with federal funds should be American-made.

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- g) Acknowledgment of Federal Support When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part by federal money, all awardees receiving Federal funds, including and not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.
- h) Recipients and sub-recipients of Federal funds are subject to the strictures of the Medicare and Medicaid antikickback statute (42. U.S.C. 1320a-7b (b) and should be recognizant of the risk of criminal and administrative liability under this statute, specifically under 42 U.S.C. 1320 7b(b) illegal remunerations which states, in part, that whoever knowingly and willfully: (A) Solicits or receives (or offers or pays) any remuneration (including kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring (or to induce such person to refer) and individual to a person for the furnishing or arranging for the furnishing of any item or service, OR (B) in return for purchasing, leasing, ordering, or recommending purchasing, leasing, or ordering, or to purchase, lease, or order, any goods, facility, services, or item for which payment may be made in whole or in part under subchapter XIII of this chapter or a State health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years or both.
- i) Clean Air Act and the Federal Water Pollution Control Act Compliance If this contract is in excess of \$150,000, Contractor agrees to comply and to require that all subcontractors have complied, where applicable, with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. § 7401-7671q.) and the Federal Water Pollution Control Act as amended (33 U.S.C. §1251-1387). Violations must be reported to the Federal awarding agency and the Regional Office of the Environmental Protection Agency (EPA).
- j) Americans With Disabilities Act This agreement is subject to the provisions of Subtitle A of Title II of the Americans with Disabilities Act of 1990, 42. U.S.C. 12132 ("ADA") and regulations promulgated pursuant thereto, see 28 CFR Part 35. The Contractor shall not discriminate against an individual with a disability, as defined in the ADA, in providing services, programs or activities pursuant to this Agreement.
- k) <u>Whistleblower Policy</u>: Congress has enacted whistleblower protection statue 41 U.S.C. 4712, which applies to all employees working for contractors, grantees, subcontractors, and subgrantees on federal grants and contracts. This program requires all grantees, subgrantees and subcontractors to: inform their employees working on any federally funded award they are subject to the whistleblower rights and remedies of the program; inform their employee in writing of employee whistleblower protections under 41 U.S.C. 4712 in the predominant native language of the workforce; and Contractors and grantees will include such requirements in any agreement made with a subcontractor or subgrantee.

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

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

19. Required Federal Certifications -

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

- a) The Contractor is not presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from covered transactions by any Federal department or agency.
- b) The Contractor is not delinquent on any Federal debt.

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

http://www.hhs.gov/sites/default/files/ocr/civilrights/resources/specialtopics/lep/lepguidance.pdf.

j) Equal Employment Opportunity, requires compliance with E.O. 13672 "Further Amendments to Executive Order 11478, Equal Employment Opportunity in the Federal Government, and Executive Order 11246, "Equal Employment Opportunity", and as supplemented by regulations at 41 CFR part 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor."

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

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Grants Gateway Expenditure Budget Instructions – Attachment 10

This guidance document is intended to help applicants with understanding the types and level of detail required in Grants Gateway for each individual budget line. For Grantee questions and instructions about entering an application in the Grants Gateway, please go to <u>https://grantsreform.ny.gov/Grantees</u> for more training and guidance resources.

Please be aware of the following:

- AIDS Institute Program Managers may require additional information or clarification necessary for approval of requested amounts on funded applications; and
- The allowability of costs are subject to the OMB Uniform Guidance.

Grants Gateway Categories of Expense

There are two major Budget Categories, Personal Services and Non-Personal Services. Each of these categories include individual sub-categories for more specific budget items that can be requested in a budget. Each line requires different information.

- 1. Personal Services
 - a. Salary (including peers who receive W2s)
 - b. Fringe
- 2. Non-Personal Services
 - a. Contractual (subcontractors, peers who receive 1099s, etc.)
 - b. Travel
 - c. Equipment
 - d. Space/Property & Utilities
 - e. Operating Expenses (supplies, audit expenses, postage, etc.)
 - f. Other (indirect costs only)

Guidance on allowable expenditures can be found in the "Basic Considerations for Allowability of Costs" document. This document can be found here: <u>http://www.ecfr.gov/cgi-bin/text-idx?SID=1728c16d0aca3b9aabbd3c25d38d5483&mc=true&node=pt2.1.200&rgn=div5</u>.

Title 2 \rightarrow Subtitle A \rightarrow Chapter II \rightarrow Part 200 — UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS, Subpart E - **Basic Considerations, §200.402** - §200.475

PERSONAL SERVICES - SALARY

For each salary position funded on the proposed contract, provide the following:

Details:

- **Position/Title:** Enter the title and the incumbent's name. If the position is yet to be filled, enter "TBH" (to be hired.)
- **<u>Role/Responsibility:</u>** Enter the position description, including the duties supported by the contract.

Financial:

- <u>Annualized Salary Per Position</u>: Enter the full salary for 12 months regardless of funding source.
- <u>STD Work Week (hrs):</u> Enter the standard work week for this position regardless of funding. If it is a full-time position, this is often either 35, 37.5 or 40 hours per week. If it is a part-time position, enter the expected number of hours per week the person will work.
- <u>% Funded:</u> Enter the percent of effort to be funded on this proposed contract.
- **<u># of Months Funded:</u>** Enter number of months this position will be funded during the proposed contract period. Use months only; do not use pay periods.
- <u>Total Grant Funds</u>: Enter the total amount for this position requested during the proposed contract period. Grants Gateway will not automatically calculate this. Please check your calculation for accuracy.

Items to Note:

- The Total Match Funds and Total Other Funds lines are not used. You will not be able to enter information on those lines.
- While Grants Gateway does not calculate the Line Total, it does calculate the cumulative Category Total.

PERSONAL SERVICES - FRINGE

Details:

- **Fringe Type/Description:** Enter a description (examples, fringe rate, union fringe rate, nonunion fringe rate, part-time fringe rate, full-time fringe rate) and the percentage.
- <u>Justification</u>: Specify whether fringe is based on federally approved rate, audited financials or actual costs.

Financial:

<u>Total Grant Funds</u>: Enter the total amount of fringe requested for this proposed contract period.

CONTRACTUAL

Details:

- <u>Contractual Type/Description:</u> Enter the name of the agency, consultant or TBA (if not yet selected). Use a separate Contractual line for each subcontractor or consultant. Include an estimated cost for these services.
- **Justification:** Briefly describe the services to be provided.

Financial:

• **<u>Total Grant Funds:</u>** Enter the total amount requested for the subcontractor.

TRAVEL

Details:

• <u>**Travel – Type/Description:**</u> Describe the type of travel cost and/or related expenses.

• **Justification:** Briefly describe how the travel relates to the proposed contract.

Financial:

• **Total Grant Funds:** Enter the total amount requested for the Travel item.

EQUIPMENT

Details:

- **Equipment Type/Description:** Describe the equipment and who it is for.
- <u>Justification</u>: Briefly describe how this equipment relates to the proposed contract and why it is necessary.

Financial:

• **<u>Total Grant Funds:</u>** Enter the total amount requested for this Equipment item.

Items to Note:

- Equipment is defined as any item costing \$1,000 or more.
- Rental equipment (if applicable) can be included in this section.

SPACE/PROPERTY RENT or Own

Details:

- <u>Space/Property: Rent or Own Type/Description:</u> Describe the property, whether it is the agency's main site or satellite and provide the address. Use a separate Space line for each different location.
- <u>Justification</u>: Explain why this proposed contract is paying for the space costs at this location.

Financial:

• **<u>Total Grant Funds</u>**: Enter the total amount requested for this Space/Property item.

<u>UTILITY</u>

Details:

- <u>Utility Type/Description:</u> Describe the utility expense.
- **Justification:** Indicate the property address for which this expense will be incurred.

Financial:

• **<u>Total Grant Funds</u>**: Enter the total amount requested for this Utility item.

OPERATING EXPENSES

This section is used to itemize costs associated with the operation of the program, including but not

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limited to insurance/bonding, photocopying, advertising, and supplies.

Details:

- **Operating Expenses Type/Description:** Describe what is being purchased.
- 1. Supplies Briefly describe items being purchased.
- 2. Equipment Include all items with a total cost under \$1,000, including computer software. Use a separate line for each group of items.
- 3. Telecommunications Include costs for all telephone lines funded by this proposed contract, fax and modem lines, telecommunications installation costs, hotlines, long distance, cell phones, and internet expenses.
- 4. Miscellaneous Includes postage, printing, insurance, equipment maintenance, stipends, media advertising, recruitment, or other appropriate costs.
 - For incentives, briefly detail the types of incentives to be purchased and what they will be used for.
- **Justification:** Describe how this item relates to the contract and why it is necessary.

Financial:

• **Total Grant Funds:** Enter the total amount requested for this Operating Expense item.

Items to Note:

Participant Support and Incentives – the following chart is in accordance with AIDS Institute policy:

Туре	Allowable using State Funding?
Participant Support	
Food Vouchers	YES
Pharmacy Cards	YES
Metro Cards	YES
Gasoline Cards	YES
Bus Passes	YES
Incentives	
Gift Card – non-cash	YES
Cash or Cash equivalent (e.g., VISA Card)	NO
Movie Tickets	NO
Theater Tickets	NO
Promotional Items *	YES*

*Promotional items must be promoting a specific program or intervention, such as Ending the Epidemic, or HIV testing, or Know your Status, rather than generically promoting the organization.

• Reimbursement for employee parking at regular work site or transportation costs to and from work is not allowable on AI contracts, unless the employee is in travel status as defined by agency's Policies and Procedures.

• Reimbursement for refreshment for employee or the Board of Directors (BOD) is not allowable. This includes food, coffee, tea, and water for staff meetings, staff break areas, or BOD meetings.

<u>OTHER</u>

Details:

- <u>Other Expenses Type/Description:</u> This section will <u>only</u> be used to document Indirect Costs. Enter the words "Indirect Cost rate" and the rate being requested.
- <u>Justification</u>: Enter whether or not this rate is based on a federally approved rate agreement.

Financial:

• **Total Grant Funds:** Enter the total amount requested for this Expense item.

Items to Note:

- Up to 10% MTDC is allowed for all applicants.
- Up to 20% is allowed if applicant has a federally approved rate that can justify the request.
- No cost that is billed directly to this contract can be part of the indirect rate.