HIV & COVID-19: REQUEST FOR RESEARCH PROPOSALS

Application Guide

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How to Use the Application Guide

The application guide contains the information you will need to complete your proposal. Understanding the application process and the ViiV Healthcare investigator sponsored research (ISR) external portal is critical to successfully submitting your application. We strongly encourage you to review the contents carefully.

Use this application guide to understand:

- How to use the ViiV Healthcare ISR external portal
- How fill out the forms and submit study proposals in system
- What information is required in each application proposal
- How to complete the ViiV Healthcare Budget Tool
- Application review and notification process

If you have any questions not addressed in this application guide, questions can be submitted to: **covid19grfp.research@viivhealthcare.com.**

Request for Proposals Priority Areas

Areas of interest for the HIV & COVID-19 RFP include but are not limited to

- Epidemiology and Real-World Data (RWD)
    - Cohort studies (focus on HIV and COVID-19 coinfection) addressing treatment and management
    - Use of institutional chart reviews & electronic databases for risk factor analysis
    - Natural history of COVID-19, comparing those with and without HIV

- Health care systems management initiatives addressing patient care and outcomes in the COVID-19 environment:
    - Digital solutions and telemedicine
    - Implementation science
    - Management of co-morbidities
    - Patient experiences and characteristics of patient-provider interaction

- Biomarkers indicative of disease susceptibility, severity, progression or mechanism
    - Predictors of disease progression of Covid-19 in PLWHIV
    - Predictors of response to SARS-CoV-2 or COVID-19 therapy
    - Role of genetic traits
    - Association of cellular immune markers with response
    - Association of inflammatory and other biomarkers with response

Eligibility Criteria

Applicant Eligibility

Applicants must be affiliated with a clinical institution and are strongly encouraged to partner with a researcher(s) with clinical experience in the field of HIV. The applicant's setting(s) can include a variety of health care settings, including but is not limited to:

- Hospitals
- Academic centers
- Health centers
- Private practices
- Clinics
- Pharmacies
- Correctional facilities
- Integrated health systems
- Telehealth

Project applications from both individual teams, and collaborations across multiple teams or institutions are equally encouraged. Applicants who have previously been successful in receiving ViiV Healthcare funding are eligible to apply.

Geographies of Interest

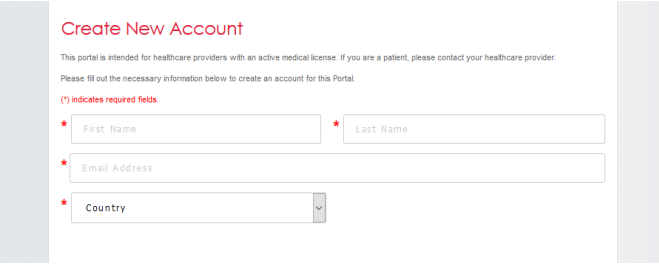
The HIV & COVID-19 RFP is a global call. We encourage applications from regions dually affected by COVID-19 and HIV, including North America, South America, Sub-Saharan Africa, Latin America & Caribbean, Europe, Middle East, and Asia

Creating an Applicant Profile

This step is only necessary if you do not already have an account on the ViiV ISR External Portal.

Step 1: Visit: ISS.viivhealthcare.com or Covid-19rfp.viivhealthcare.com

Step 2: Select the "Create Profile" menu option



Step 3: Complete the requested information and click "I AGREE"

1. Details (Investigator/Institution)
2. Medical/Healthcare Professional Certification Information
3. Conflict of Interest Check

Step 4: Follow the steps to validate your account and set your password.

Concept Submission Instructions

From the Covid-19rfp.viivhealthcare.com page select the Submit Response button. This will initiate the submission process.

Before an application can be submitted, investigators are directed back to their profile to confirm that all information is still correct. Review the information and hit the "Update Profile" button at the bottom.

Best Practice: Complete the Concept form and "Save" until other proposal documents are completed and uploaded to the "Files" tab.

Once all documents are uploaded reopen the Submission Form and "Submit". The Submission form will move from the "Editable by Investigator" tab to the "Submitted to ViiV" tab.

Title

Provide a descriptive title for the topic your study addresses.

Sponsor Institution Country

Enter the country where your institution is based.

Study Overview Details

Completed the study details. Be prepared to enter:

- Study type
- Number of subjects
- Countries were the study will take place
- Drugs (if applicable) that will be used

Background and Rationale

- Provide a brief overview of the study being proposed in about 2000 characters. Be sure to include information on:
    - Study rationale and objectives
    - Study methods and design
    - Study analysis
    - Budget requesting

Additional Information

Be prepared to answer questions regarding product and monetary support needed.

Proposal Submission Instructions

Font

The proposal must be written in 12-point Arial for legibility.

Page Limit

The proposal should be no longer than five single-spaced, single-sided pages with one-inch margins.

Format

Microsoft Word document or Adobe Acrobat PDF.

Attaching to your submission

The proposal must be uploaded to the 'Files' tab on the ViiV ISR external portal. Select your submission in the "Editable by Investigator" to access the 'Files' tab.

Proposal Template

All proposals submitted in response to the HIV & COVID-19 RFP must include the following sections:

Proposal Sections	Suggested Word Limit
Title of Research Project	25
Background	250
Objectives	150
Methods	500
Research & Analysis Plan	750
Projected Enrollment Timeline	300
Budget	25
Data Dissemination and Publication/Presentation Plan	100
References	Not included in page limit

I. **Title of Research Project**
Provide a descriptive title for the topic your study addresses.

II. Background

a. Explain the significance of the problem and explain how the proposed study will improve scientific knowledge, medical or technical capability and/or clinical practice in one or more the RFP's priority areas:
   - Epidemiology and Real-World Data
   - Health Care Systems Management
   - Biomarkers Indicative of Disease Severity

b. Describe scientific rationale for the study, including strengths and limitations of existing research. Include any preliminary data of your own.

c. Explain the setting and/or population of the proposed study and provide information regarding the importance of research within the setting and/or population.

III. Objectives

a. Clearly state the study's objectives and the types of questions it is seeking to answer:
   - Clinical questions
   - Epidemiological questions
   - Implementation questions

b. **Hypothesis** (if applicable): Please describe the hypothesis the study is testing.

IV. Methods

Succinctly but thoroughly describe the study design and methods.

a. Study design: Please identify the type of study you are proposing and fully describe the entire methodology. Please identify the methodology proposed to achieve a greater understanding of external validity at the end of the study. This RFP is open to variety of study designs, including but not limited to:
   - **a. Randomized Control Trials (RCTs):** individual randomized trails, cluster randomized trials, stepped-wedged design, effectiveness-implementation hybrid design
   - **b. Intervention optimisation:** multiphase optimization strategy (MOST), sequential multiple assignment randomized trial (SMART)
   - **c. Quasi-experimental designs:** interrupted time series, regression discontinuities, regression point displacement
   - **d. Observational designs:** cohort study, cross sectional, case-control
   - **e. Systems science approaches:** system dynamics, network analysis, agent-based modelling
   - **f. Qualitative designs:** longitudinal qualitative inquiry, in-depth interviews, focus-group discussions, observations
   - **g. Mixed-method designs:** use of both qualitative and quantitative methods and be used to inform measurement considerations and analysis rather than be proposed as a larger study design

b. Study design justification: Please provide a justification for the choice of study design.

c. Implementation research design (if applicable): Identify and justify the IS model or framework which best supports your implementation question (Examples: Consolidated Framework for implementation Research, RE-AIM, EPIS, etc.) and how it will be operationalized. Ensure to describe the implementation stage of the project (e.g., exploration, installation, full) as well as identify the design (e.g., hybrid, pure implementation research).

d. Human subject and data protection: Please describe the potential risks to participants associated with the proposed study, including the risk level, its impact on the study participants, measures to mitigate risks, and where appropriate, alternative treatments and procedures.

V. Research and Analysis Plan

Succinctly but thoroughly describe the outcomes (if applicable) and data analysis plan of the proposed study.

a. **Primary endpoints**: Clinical, epidemiological or implementation endpoints

b. **Secondary endpoints** (if applicable): Clinical, epidemiological or implementation endpoints

c. **Inclusion/Exclusion criteria**: Please describe inclusion and exclusion criteria for applicable participants e.g. patients, staff, clinics, or other unit of analysis.

d. **Sample size**: (i.e. Number of Participants/Clinics): Please describe the anticipated number of participants. This may include patients, clinic staff, clinic facilities, or other units of analysis.
e. **Statistical analysis**: Provide an overview of the proposed statistical analysis plan, please include:
    - Statistical hypotheses for quantitative studies (or if none state why not),
    - Sizing considerations,
    - Randomization (where applicable),
    - Analysis of primary and major secondary endpoints,
    - Control for bias in absence of randomization.
    - Power calculation
    - Sample size rationale for qualitative inquiries
    - Statistical methods for analyses
f. **Outcome Metrics:** Please include the following: outcomes, measurement methods, data source, and timepoints. Describe how each outcome will be specifically measured (e.g., quantitative measure, qualitative interview) rather than only listing broad categories of outcomes. Outcomes can include service, patient, and implementation outcomes.

VI. Timeline

Please be as detailed as possible, including recruitment and assessment timeline.

a. Projected enrolment timeline:

Proposed start date

Data collection timepoints

Proposed finish date

VII. Budget for Proposal

Provide only total requested budget for the implementation of the study.

VIII. Data Dissemination and Publication/Presentation Plan

Proposals should include an overview of the data dissemination and publication/presentation plan. How will your findings reach the relevant stakeholders (e.g., scientific audiences, community audiences, etc.)? Examples of information to include:

a. Conference or other dissemination platform relevant to your setting
b. Target journal
c. Timeline

IX. References

A list of references must be included with the proposal. References are not included in the five-page limit.

Curriculum Vitae (CV) or Biosketch Instructions

Applicants must provide their CV or NIH Biosketch stating relevant experience applicable to the execution of the proposed research study. A CV or Biosketch should be provided for all named principal or co-investigators of the study.

Attaching to your submission

The proposal must be uploaded to the 'Files' tab on the ViiV ISR external portal. Select your submission in the "Editable by Investigator" to access the 'Files' tab.

Budget Instructions

Budget Limits

ViiV Healthcare will prioritize research projects with funding requests less than £250,000. However, budgets above £250,000 will still be reviewed for their necessity. This is a one-time grant focused on helping our understanding and management of COVID-19 in PLWHIV.

Budget Submission

Applicants must submit a detailed budget using the ViiV Budget Tool, available on the Toolbox tab. For additional budget guidance refer to the Budget Guidance document also in the Toolbox.

Allowable Grant Costs

Grant funding can be used for, but are not limited to:

- Advertising costs for recruitment purposes
- Study related clinical insurance
- Assay reagents and other consumables for use with site's equipment
- Study close-out fee
- Supplies
- Printing fees
- Journal fees
- Personnel costs specific to the study
- Pharmacy fees (set-up costs, storage etc.)
- IRB/EC costs (initial and renewal)
- Site start-up costs
- Translations
- Patient reimbursement for visits
- Shipping
- Archiving fees
- Cost of essential study-related activities (e.g. Trial Steering Committee, site monitoring, IDMC)
- Software that is needed and will be used ONLY for the proposed study

Non-Allowable Grant Costs

Grant funding cannot be used for, but are not limited to:

- Information technology hardware, software, or services (telehealth equipment or services are considered clinical equipment, not IT). We do not purchase software for general research use.
- Travel costs

In-Direct Costs

ViiV Healthcare allows indirect costs. The indirect cost cap is 25%. Any amount over 25% will require the applicant's institution rate documentation for justification. If the request is over 35%, the rate may not be approved. Note, indirect costs are included in the budget maximum.

Fringe benefits

ViiV Healthcare does not cover fringe benefits.

Purchasing of medication for the study

Applicants cannot request ViiV Healthcare medicines for use in their proposed study.

Application Review and Notification Process

Application Timeline

Request for Proposals 27th April 2020 → Deadline for submission of applications 18th May 2020 → Notification to awardees week commensing 5th June 2020

The deadline for proposals is **12 midnight GMT** on **May 18, 2020**. Late proposals will not be accepted.

Application Evaluation Criteria

The proposal will be reviewed by an internal ViiV Healthcare scientific panel against predefined criteria and will be compared head to head with equivalent proposals, through a competitive assessment process.

Criteria	Points
Significance and alignment with at least 1 research priority	20
Approach- The quality of the methodology, design, and analyses	25
Feasibility – Well defined study scope and timeline	20
Global/regional applicability	5
Qualifications of the research team and organizational support	10
Innovation	15
Well defined and justifiable research costs	5
Total	**100**

Frequently Asked Questions

I submitted a strong proposal, why was my application not funded?
Proposals will be reviewed by an internal ViiV Healthcare scientific panel against predefined criteria and will be compared head to head with equivalent proposals, through a competitive assessment process. As such, not all proposals, including strong proposals, will be successful.

Can I use this application to request medicines for compassionate use for COVID-19?
The HIV and COVID-19 RFP is specifically for the conduct of research to help improve our understanding and management of COVID-19 in people living with HIV (PLWHIV). If an applicant is solely interested in medicines for compassionate, please contact one of ViiV Healthcare's Medical Science Liaison.

Can one institution submit multiple applications?
Yes. However, proposals from the same institution should be substantively different and an investigator cannot be the principal investigator on more than one approved award.

Will I receive the score or review comments from my application?
Please note that we will not release application scores or reviewer comments.

What is the difference between the RFP ISS vs. the Open ISS Process?
The RFP is a competitive process, where ViiV Healthcare requests applications on timely and important areas of interest. The Open ISS is an unsolicited process, whereby applicants submit their research applications to ViiV Healthcare for consideration.
A scientific panel reviews applications under both processes and not all proposals are successful.

If my proposal is not selected, can I resubmit my application to the Open ISS?
Yes. However, we strongly encourage applicants to discuss their proposal with a ViiV Healthcare representative before submitting to the Open ISS.

Can I collaborate with other institutions to submit a proposal?
Yes.

What is the expected funding period for the RFP?
This is a one-time grant focused on helping our understanding and management of COVID-19 in PLWHIV. while there is a pandemic. If you anticipate your research project will extend substantially beyond the pandemic or take a considerable length of time to complete, you might want to consider applying for our Open ISS.

Where can I find instructions on how to complete the ViiV Budget Tool?
Instructions are located on the "Instructions" tab in the ViiV Budget Tool. You can also refer to the Budget Guidance document.

Can I use my institution's budget tool?
No, in order to complete our Fair Market Value analysis, we require all budgets on the ViiV Budget Tool.

How can I track the progress of my proposal?
The current status of your proposal is available by selecting "My Submissions" and locating your submission by its title. Additionally, the system will send status update emails when the statuses change. A Status of 'Proposal Under Review' indicates that your submission packet is complete.

If during the internal ViiV scientific review process, the reviewers reach out to me and require some additional information and clarifications on my proposal, does this mean my proposal will be accepted if I provide these clarifications?
No.