ViiV Investigator Sponsored Research (ISR) Proposal Supplementary Information Form

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| * This form collects supplementary information when a protocol is submitted instead of an ViiV Investigator Sponsored Research (ISR) proposal template. As you complete this template, please ensure that you take into consideration the guidance provided in each section, to facilitate the timely review of the study proposal. Once completed, this form and current version of the study protocol should be submitted as components of a ViiV ISR Proposal application, via the [ViiV Investigator Sponsored Research (ISR) portal](https://iss.viivhealthcare.com).
* All proposals submitted to ViiV Healthcare are reviewed by a review committee comprising scientific and clinical experts, including statisticians, physician scientists, safety scientists, virologists, clinical pharmacologists, translational medicine scientists and others.
* Please note that ViiV’s support of a study proposal is to address data gaps and therefore, it is the expectation that all studies will need to generate conference abstracts and at least one manuscript that includes the primary study outcomes for journal publication. If your study involves a ViiV medicine, then ViiV will be required by law to include such publications in periodic reports to the FDA, EMA and other regulatory authorities. ViiV is committed to fulfilling these regulatory reporting requirements in a timely manner consistent with the efficient and timely conduct and performance of a study.
* ViiV, as development product owner and/or Marketing Authorisation Holder, has a responsibility to collect and analyse safety information on its Medicinal Products. This is so that the company can fully understand the risk-benefit profiles for its products and can provide accurate safety information to: study Investigators and participants; ethics committees; regulatory authorities; and prescribing physicians and their patients. As such, if your study involves a ViiV medicine, ViiV may provide requirements for safety reporting that will need to be included in the protocol as well as legal agreements, as outlined in the [linked document](https://viiv-portal.idea-point.com/Documents/ViiV%20ISR%20Safety%20Requirements.pdf).
* When a proposal is approved, ViiV may require a subsequent draft of the protocol to perform an additional, more detailed review (and informed consent form for Interventional studies), prior to submission to ethics or institutional review board. For all studies, final study approval is subject to successful execution of a legal agreement between ViiV and the Sponsor. With the exception of non-clinical studies involving pure drug substance, please ensure that you and your contracts office review the general terms and conditions in the [linked document](https://viiv-portal.idea-point.com/Documents/ViiV%20ISR%20Term%20Sheet.pdf) BEFORE you submit this proposal. Failure to review and understand the requirements will result in unnecessary delays to starting research in a timely manner and may jeopardize the viability of the research project.
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1. RESEARCH QUESTION/INNOVATION

What is the critical research question that will be addressed by the proposed research? Explain what is innovative about your proposed approach for the current research proposal. You may include a brief review of any other studies completed (e.g., the strengths and limitations of the existing research). Please state the impact of your study if the results generated are as planned. If all this information is included in the protocol, then please cross-refer.

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| Add text |

1. FEASIBILITY

Describe the actions taken to ensure the feasibility of the current research proposal. Describe any preliminary data that demonstrates the feasibility and ability of successfully conducting the proposed research. Include any foreseen challenges and strategies to overcome these. Please describe what efforts will be made to facilitate the enrolment of representative participants into the study.

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| Add text |

1. Additional Details on Interventions

Please provide further details on the following in your study design. Interviews, questionnaires, surveys, blood/urine samples and participant follow-up can be considered normal clinical practice, so long as the application of these is not conducted in a way that differs significantly from standard-of-care. Invasive procedures such as collecting biopsies or cerebral spinal fluid, or performing scans, x-rays or barium meals would have to be conducted as standard-of-care to be considered normal clinical practice.

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| **ViiV Healthcare (VH) Medication(s)***Specify the regimens, including drugs and doses (broken down by arms, if applicable), and specify the duration of treatment. Specify if VH medication(s) will be assigned to study participants per protocol, or if the decision to treat with VH medication(s) will be independent of study participation and in accordance with both standard of care and local prescribing information? OR if only generic versions of VH medication(s) will be used* |
|       Add text |
| **Patient reported outcome measures.***Please specify if instruments planned for use are validated or not, if licenses are required, and if they are considered normal clinical practice for the study participants (see note at the top of this section)*.  |
|       Add text |
| **Other surveys or questionnaires***List any other tools that will be used that are not considered normal clinical practice for the study participants (see note at the top of this section).* |
|      Add text |
| **Exposure to ionising radiation***Will the proposed study involve ionising radiation exposure (e.g. X-rays, positron emission tomography [PET], dual-energy X-ray absorptiometry [DEXA], or computed tomography [CT] scans)? Please specify if these are considered normal clinical practice for the study participants (these would have to be conducted as standard-of-care to be considered normal clinical practice).* |
| Add text |
| **Biological tests and/or diagnostic procedures***List clinical & biomarker measures and/or diagnostic procedures that are not considered normal clinical practice for the study participants (see note at the top of this section).* |
| Add text |

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| **Detailed Implementation Science Strategies and Frameworks***Please refer to the linked* [*Implementation Science guidance*](https://viiv-portal.idea-point.com/Documents/Implementation%20Science%20Proposal%20Guidance.pdf) *document to describe the implementation strategies, the frameworks, and research methods planned. If this information is included in the protocol, then please cross-refer.* |
| Add text |

1. Study Timelines

Please provide details of timings for achieving key milestones in study (e.g., proposed start date, enrolment duration, data collection timepoints, study end date). If your proposal is approved by ViiV, please note that a legal agreement will need to be in place before the study can begin and funding is paid to the institution. Please factor no more than 6 months to execute the study agreement in your study timelines. Please be sure to communicate to your contracts office that proposals which fails to achieve a fully executed agreement by 6 months after approval may be subject to further re-evaluation of support and may be at risk of defunding depending on strategic priorities. Below is the minimum expected planned milestones. Please add any additional milestones at your discretion.

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| Milestone | Planned Date6 |
| EC/IRB Submission (This can be actual date if already approved) (N/A for non-clinical studies) |  |
| EC/IRB Approval1 (This can be actual date if already approved) (N/A for non-clinical studies) |   |
| Study Start Date2 |   |
| Enrolment Complete |   |
| Primary Completion3 |   |
| Study End4 |   |
| Report Complete5 |  |

1. Approval = Date of Final Protocol or Final Analysis Plan approved by 1st ethics committee (EC)/IRB or equivalent Sponsor approval committee
2. Start Date = First Participant First Screening Visit (or Data Collection Starts for studies where no participants will be recruited)
3. Primary Completion = Date on which data collection is completed for all the primary outcomes. This date may occur prior to Study End (SE) milestone or be the same date as the Study End milestone.
4. Study End = Last Participant Last Visit (or Data Collection Ends for studies where no participants will be recruited)
5. Report Complete = Date of Submission of Primary Manuscript or Study Results Summary (as defined in Contract)
6. Planned Date = Date the milestone is planned to be completed
7. Data Dissemination and Publication/Presentation Plan

Include an overview of the data dissemination and publication/presentation plan.

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| Type of Data/Endpoint/Interim or Final | Abstract or Manuscript | Target Conference or Journal  | Estimated Submission (Quarter/Year) |
| E.g. Interim 24-week clinical & safety dataE.g. Baseline characteristics of cohort | AbstractManuscript | EACS 2025AIDS Patient Care | 2Q20253Q2025 |
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