ViiV Investigator Sponsored Studies (ISS) Proposal Template

Proposal pages should have 1-inch margins & Normal style 12-point Arial font, single spaced. Proposals must include the Level 1 Heading sections identified below (at a minimum). If section is “not applicable to the type of study, enter “N/A” under Level 1 Heading Text in this font (Style = Guidance Notes) and the template title above this section can be deleted. Level 1 Headings should not be modified. Level 2 headings can be added as appropriate.

# Title of Research Project

Provide a descriptive title for the topic your study addresses. Note: This title should align with the title entered on the ISR portal.

# Scientific Rationale

Provide a brief summary of the overall purpose of this proposed study and any background information that led to this proposal

# Hypotheses

Provide a description of the hypothesis that you will be testing in this study.

# Objectives

Provide a brief summary of the primary and key secondary objective(s) for this proposal and/or what the study is expected to demonstrate.

## Primary Objective

## Secondary Objectives

# Study Endpoints

Describe the variables that will be used in the primary analysis and any important secondary analyses, statistical approaches that will be used to analyze them, and conclusions that will be drawn given one or more of the possible outcomes

# Study Design

Describe the general study design, study groups/arms, main tests or procedures, primary and important secondary outcome variables, design justification, and general approach to analysis

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

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).

# Statistical Plan

Provide the target sample size for each group of study subjects, animals or experiments. Justify the total sample size on the basis of statistical power to test the primary hypothesis (and important secondary hypotheses, if relevant) using the stated primary and/or secondary outcome variables.')

# Population

If applicable, provide a general description of the participants to be enrolled (e.g. number of subjects, subject demographics such as age, sex, and other key characteristics, and other key eligibility criteria (inclusion and exclusion criteria)). Describe sources and process for recruitment. The information provided should justify selection of participants and provide assurance that an appropriate number of eligible participants can be recruited.

# Study Intervention/Product Regimens

If applicable, provide a brief summary of the therapeutic entity(s) and regimen(s), including any proposed controls that will be used in the proposed study.

# References

Include references to any existing published studies and any other background information you believe is relevant to the review of this proposal.