ViiV Pure Substance Request (PSR) 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 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

**If available**, investigators should upload a study design schematic. The design schematic can be uploaded on the files tab similar to this proposal document. If provided please provide the file name in the information within this section.

# 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.')

# References

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