

Required Principal Investigator RNA Study Plan Preparation Outline

Purpose: The administrative purpose of a study plan is to document an *agreement* among all involved by clearly describing what is to be done, why and to whom it is important, who is going to do what, and what expected results and products are likely to result from the work.

The technical purpose of a study plan is to provide a detailed plan for conducting the research. In most applied research this plan should also provide a clear and convincing case that the plan will answer the research questions posed in the study plan (i.e., reach the stated objectives) for some well-defined population with the resources available for conducting the study. Proper development and use of study results also require a clear statement of purpose and description of methods.

Content: A study plan should clearly specify the objectives of the study and how they integrate or link with other research, methods to accomplish the objectives, and uses of anticipated results. A study plan should also identify means of minimizing environmental health and safety hazards associated with the research.

Specificity: A question often arises about how detailed and specific a study plan should be. A useful rule of thumb is that a study plan should be sufficiently detailed, about all aspects of the methods, so that another professional, with similar experience, could assume responsibility for the plan, at any point in time, and successfully complete the study as planned.

An outline of a study plan is:

I. Title.

II. Literature. Briefly review pertinent literature and applicable current studies to explain the rationale and importance of the study objectives and benefits of a successful study. This information can be a succinct summary obtained from the Problem Analysis with appropriate reference to the Problem Analysis.

III. Objectives. State immediate objective as questions the research is to answer.

IV. Methods. Clearly describe: source and reliability of any existing data or information that will be utilized; experimental or sampling design if new data are to be obtained, with specific attention given to sample sizes needed; how data or other analyses will be conducted to answer the questions posed in the objectives; and assumptions required to conduct the analyses and any constraints on their interpretation.

V. Quality assurance/quality control procedures. List measurement quality objectives for all measurements. Describe training needs and plans, if training is needed. Give references to proposed laboratory standards and equipment calibration routines (where appropriate). Describe any proposed audits or quality control sampling schemes where applicable, or other methods used to assess the degree to which collected data will meet the stated measurement quality objectives. Provide data dictionary information. Describe data validation/verification procedures.

VI. Application of research results. Discuss content and form of anticipated results, who will benefit, how best to communicate the results to these clients and cooperators, and linkages to other research.

VII. Safety and health. Identify safety and health hazards associated with the study, and describe ways to deal with them during the study. If available, the relevant job hazard analysis should be referenced or included.

VIII. Archiving and Data Management. All data, reports, publications, etc. resulting from RNA studies must be submitted electronically for archiving as described in the approval process. Acceptable formats are plain text (.txt), Rich Text (.rtf), Adobe (.pdf), Microsoft Word (.doc) or Excel .xls formats. (Excel format is for data only.)