Key Elements of a Research Protocol

All protocols must include the following:

- Project Title.
- Name and contact information of the Principal Investigator and any co- or sub-investigators (including students).
- Location of the research site(s) and identification of any institutions other than Baylor involved in the research.
- A version number and/or date.
- All pages must be numbered.

I. Background and Rationale
   a. This section specifies the reason(s) for conducting the research. It should explain the purpose of the research, the research question(s), and how this research will contribute to existing knowledge.
   b. Include previous research (e.g., pre-clinical and clinical studies) leading up to and supporting the purpose of the research.
   c. Rationale for conducting the research (including the potential benefits to individuals, society, literature, etc.).
   d. This section is the equivalent to the introduction to a research paper and would put the proposal into context. It should only include references and descriptions of the most relevant studies that have been published on the subject.
   e. References and/or literature search can be placed in a section/appendix at the end of the protocol. There is no need to list an extensive literature search for simple studies.

II. Research Objectives (Specific Aims or Goals)
   a. Specify the objectives or aims in the research study (the key research questions being answered). Objectives should be simple and specific (not vague), and be tied to the statistical analysis.
   b. List and number individually.
   c. May include Primary and Secondary objectives.

III. Subject Selection and Recruitment
   a. Identify the subject population targeted for the research (include total enrollment numbers and any group/cohort breakdown numbers).
   b. If not recruiting actual subjects (e.g. database query for eligible tissue samples, secondary analysis of existing data), state what will be queried, and how and by whom eligible samples/data will be identified.
   c. If you are excluding a particular population (such as males or females, non-English speakers, women of child-bearing potential, or pregnant women) provide a scientific justification for the exclusion.
   d. If including any vulnerable populations (children, pregnant women, prisoners, diminished capacity, non-readers, etc.), state why their inclusion is important, any specific benefits, and any additional protections.
   e. Specify how subjects will be selected, i.e. the inclusion and exclusion criteria.

i. Inclusion/exclusion criteria should be as specific as possible and include definitive parameters.

f. Methods for recruitment and enrollment.
g. Consent process & procedures.
h. Describe any randomization processes.
i. Sampling (if applicable): explain how sampling will occur.
j. Describe how withdrawals of subjects will be handled.

IV. Research Methods & Procedures
   a. Explain the study design and choice of methodology (may include a study schema to provide an illustration).
   b. Describe any measures taken to eliminate bias.
   c. State the study duration/timeline.
   d. If there is deception, placebo, or a sham procedure, provide the rationale, the process, and any de-briefing measures.
   e. Any test articles being studied, such as:
      i. Drugs (dose, method, schedule of administration, dose modifications, toxicities).
      ii. Devices.
      iii. Supplements (dose, method, schedule of administration, dose modifications, toxicities).
      iv. Food or color additives.
   f. All tools and study measures must be identified and described. For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this research.

V. Study Visits (if applicable)
   a. Describe the study visit(s), including:
      i. The procedures and/or interventions to be performed.
      ii. The parameters to be measured (e.g., lab tests, x-rays, or other testing).
      iii. Administration of questionnaires, surveys, etc.
      iv. The data that will be collected.
   b. May include a schedule of assessments chart to illustrate which procedures occur at a visit.

VI. Risks and Benefits
   a. Risks and discomforts (stratify by common and uncommon).
      i. Include all non-medical risks – psychological, legal, social, financial, etc.
      ii. Include all medical risks, such as:
         (1) Complications of surgical and non-surgical procedures.
         (2) Drug side effects and toxicities.
         (3) Device complications/malfunctions.
         (4) Radiation risks.
      iii. If risks/discomforts are listed in a separate document (e.g., investigator's brochure or device manual), this section can be omitted.
      iv. Describe how incidental findings will be handled.
   b. Benefits

i. Potential benefits to the individual participants.
ii. Potential benefits to society.

VII. Statistical Analysis
   a. Specific data variables being collected for the research (e.g., data collection sheets).
   b. How the data will be managed, including data handling and coding for computer analysis, monitoring and verification.
   c. Clearly outline the statistical methods to be used, including:
      i. Rationale for choice of sample size (power calculation and justification).
      ii. Level of significance to be used.
      iii. Procedures for accounting for any missing or spurious data.
   d. Provide criteria for study termination (e.g., stopping rules).
   e. For projects involving qualitative approaches, specify how the data will be analyzed.

VIII. Data Management & Privacy/Confidentiality
   a. Describe the data and/or biological samples collection methodology (including who will perform what tasks and who will have access to the data).
   b. Describe data protection/security plans.
   c. Provide the length of time the data and/or samples will be kept.
   d. Describe whether data and/or samples will be kept confidential (i.e., data/samples can be potentially linked to participants, such as through a code key) or anonymous (i.e., impossible to link data/samples to participants).
   e. If data and/or samples will potentially be shared with other researchers in the future for research purposes not detailed in this study, you must include an explanation.
   f. If data/samples will be destroyed, describe when and how destruction will occur.
   g. Describe recordkeeping and record retention plans.

IX. Data & Safety Monitoring
   a. Include whether there will be independent monitoring of the source data (e.g., independent monitor, data monitoring committee, data and safety monitoring board (DSMB), etc.).
   b. Procedures for reporting deviations from the approved study plan.
   c. Procedures for recording and reporting unanticipated problems and/or adverse events.

X. References

XI. Appendices
   a. May include:
      i. Data collection forms, case report forms (CRFs).
      ii. Study tools (e.g., questionnaires, surveys, etc.).
      iii. Detailed specimen processing and/or banking procedures.
      iv. Instructions for procedures or devices.
      v. Literature searches.