

# General Prospective Protocol Template

*Note: There are no specific length recommendations/requirements for a protocol other than to use as much detail as possible in your writing. Your audience is the research and institutional review committee. The Consent form must be written for the research subject at a 6<sup>th</sup> grade education level.*

## Section I: Scientific Design

- A. **Title** Descriptive title, principal investigator(s), co-investigator(s), other study personnel
- B. **Table of Contents** (if >10 pages)
- C. **List of Abbreviations**
- D. **Brief Summary/Abstract** Briefly discuss the overall rationale
- E. **Specific Aims/Objectives** List aims and hypotheses, define trial objectives
- F. **Background and Significance** Prior research on topic
- G. **Preliminary Studies** Feasibility, any pilot studies
- H. **Drug Supply, Packaging, Labeling and Storage** How study drugs are obtained, bottled, etc.

## Section II: Investigational Plan

- A. **Overall Study Design and Methods** Describe Study design and who, what, where, when, and how. Refer to appendix A, the Study Calendar. Include a schematic diagram if design is complex.
- B. **Selection of Subjects** Define your subject population and provide a list of inclusion / exclusion criteria
- C. **Observations and Measurements** When assessments for treatment affect will be done
- D. **Data Collection Plan** Describe collection instruments, hardware / software, data security
- E. **Statistical Methods** How analysis will be done, statistical significance
  - a. **Power/Sample Size Considerations** Calculation (assumptions, power level, alpha level, etc.)
  - b. **Statistical Analysis Plan** Describe the statistical methods to be used
- F. **Publication and Presentation Plan** Planned meetings, conferences, journal publications
- G. **Timeline** When you expect to complete the study, include key milestones

## Section III: Human Subject Information

- A. **Human Subjects**
  - a. **Inclusion/Exclusion criteria**
  - b. **Gender/Minority/Pediatric Inclusion** Describe if inclusion of women, children, and minorities
  - c. **Recruitment and Consent** How subjects will be recruited
- B. **Risks and Benefits** Describe risks and assess likelihood and seriousness.
  - Describe procedures for protecting against or minimizing potential risks.
  - Describe potential benefits and importance to the subjects and others.
  - Discuss why risks are reasonable in relation to benefits.
  - Describe consent form process
- C. **Data and Safety Monitoring Plan** You may use your Sponsor's plan, or describe plans for the following
  - a. **Adverse Event (AE) Reporting:**
  - b. **Risk Minimization**
  - c. **Monitoring of Study Implementation and Progress**
  - d. **Study Termination** Early withdrawal of individuals
  - e. **Confidentiality** Protected Health Information and Health Insurance Portability & Accountability (HIPAA)
  - f. **Data Security** Measures used to protect study data from loss or inappropriate use
  - g. **Record Retention** Plan to retain study essential documents, QMC policy is 7 years

## Section IV: QMC RIRC Informed Consent

### Consent Form Template, including language for HIPAA Compliance

*Please use the QMC RIRC template given in the General Prospective Protocol Guidelines*

*All text is written for the research subject, at a 6<sup>th</sup> grade education level*

- A. Title of Study** T
- B. Principal Investigator**\_ Name, Address, Phone
- C. Sponsor** Name, Address
- D. Informed Consent Text**
- E. Purpose of the Study description**
- F. Procedures** Screening, study treatment, follow-up visits, early termination
- G. Risks** Complications of drugs, treatment, equipment, risks may be not known yet
- H. Benefits** You may feel better but no guarantee
- I. Other Treatment** Describe other treatments, options available. Include the option to not do anything
- J. Confidentiality** Study-related records will be kept according to all applicable laws
- K. Use And Disclosure (Release) Of Your Health Information**
- L. Access To Your Information**
- M. Costs** Outline what the sponsor pays for, and what the patient pays for
- N. Treatment And Compensation For Injury** If you are injured as a result of this study, you will get;
- O. Removal From The Study** You may be taken off the study without your consent for any of the following;
- P. New Findings** You will be told of any important new information
- Q. Who To Contact** List who must be called
- R. Signature Page** Agreement to take part and certification and authorization of PHI
- S. Surrogate Signature Page** If subject is unable to consent

## Section V: Attachments and Appendices

- A. Study Calendar** – List all visits (screening, treatment, endpoint, and follow-up) and the procedures to be done
- B. Budget Page** - Brief description of fees (i.e. chart archives fee, researcher hourly fee, etc.) and/or balance sheet
- C. Curriculum Vitae** - of Principal Investigator and other research personnel with patient or data contact
- D. Roles of Personnel** - Also specify any privileges that will be needed (i.e. Allied Health Professionals credentialing, Care\*Link training and access required)
- E. References** - List only the literature cited within your Protocol's text.  
Use the NIH format: names of all authors, title, book or journal, volume, page, and year.
- F. Data Guardian Approval** - Approval from Data Guardian(s), signed agreement letter should be attached.
- G. Data Collection Forms** - Data collection tools, forms, or screen prints.