**A GUIDE TO WRITING A RESEARCH PROTOCOL**

The purpose of this template is to assist investigators and study personnel in planning and conducting research projects. It is important to note that:

* Time spent on writing a detailed protocol will avoid problems during the study conduct, help the IRB give your project guidance, and make each step of the study process simpler, from data collection to publication, if applicable.
* Be sure to include all information needed and a complete protocol. An IRB packet should only be submitted once you know your complete protocol and understand your research study fully. Insufficient protocols or evidence of lack of thought given towards your study will result in your packet being refused.

Some sections of this document may not apply to your study. This document and its formatting are designed to provide you with guidance and may not be complete.

**General comments**

* Be sure to update the footer to include the most up-to-date version information.
* Make sure the information given in each document sent to the IRB matches and is accurate. Inconsistent applications will be refused.
* Yellow-highlighted content is for reference only and must be deleted from the final Research Protocol Document.
* Be sure to include copies of all data collection sheets, questionnaires/surveys, or any other research tools in the Appendices.

**DELETE THIS PAGE FROM FINAL DOCUMENT! This is for instructional purposes only!**

**PROTOCOL TITLE HERE**

 (REMINDER: **Yellow highlights indicate instructions and should be deleted before submission. Delete any sections that do not apply to your research project!)**

PRINCIPAL INVESTIGATOR: Name

Address

Phone #

Fax #

Email

CO- or SUB-INVESTIGATORS: Name(s)

Institution(s)

Address

Phone #

Email

FACULTY ADVISOR (if student-led research): Name

Address

Phone #

Email

FUNDING AGENCY: Name

(List any financial support (i.e. grant or company))

PROTOCOL VERSION: Date

(Date refers to the date the protocol is complete. If any edits are made, update this date accordingly.)

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(May be revised and re-numbered as necessary, but should include applicable major sections)

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**BACKGROUND AND RATIONALE**

* Explain the purpose of the research and the research question(s)
* Include background information and research that has led to your current project. You must provide sufficient information so someone unfamiliar with your field of study will have the baseline understanding to read this protocol. Providing insufficient background information will result in your IRB packet being refused.
* Why you are conducting the research and its potential benefits to individuals, society, literature, etc.
* You should include citations of peer-reviewed information. With this said though, this is not a full literature review, so focus on the most pertinent information that applies to the current study.
* Citations will go in the references section of this document.

**STUDY OBJECTIVES**

* List and number the key research objectives. Objectives should be simple and specific (not vague).

**SUBJECT SELECTION & RECRUITMENT**

***INCLUSION CRITERIA***

***EXCLUSION CRITERIA***

* Identify the subject population targeted for the research (include total enrollment numbers and any group numbers).
* If not recruiting actual subjects (i.e. a database or preexisting samples), state what, how, and by whom eligible samples/data will be identified.
* If you are excluding a particular population (such as males or females, non-English speakers, women of childbearing potential, or pregnant women), provide a scientific justification for the exclusion.
* 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.
* Specify how subjects will be selected, i.e., the inclusion and exclusion criteria.
  + Inclusion criteria refers to what characteristics are required of a participant (i.e. a study that requires physically fit individuals might have inclusion criteria of participants exercising three or more times per week for at least an hour each session.)
  + Exclusion criteria refers to what characteristics would prevent someone from enrolling in the study (i.e. a study requiring the consumption of wheat bread would have the exclusion criteria of a known wheat allergy)
* How will you recruit and enroll participants?
* Consent process & procedures. Information should include:
  + Location and circumstances of the consent process (e.g., private setting, group setting, online, through email or postal service, over the phone, etc.)
  + How will it be ensured that the subject has sufficient opportunity to consider whether to participate.
  + How possible undue influence or coercion will be minimized.
* Describe any randomization processes, if applicable.
* Describe how withdrawals of subjects will be handled.

**RESEARCH DESIGN & METHODS**

* Explain the study design and choice of methodology (may include a study schema to provide an illustration).
* State the study duration/timeline.
* If there is incomplete disclosure, deception, placebo, or a sham procedure, provide the rationale, the process, and any de-briefing measures.
* Any test articles being studied, such as:
  + Drugs (dose, method, schedule of administration, dose modifications, and toxicities).
  + Devices.
  + Supplements (dose, method, schedule of administration, dose modifications, and toxicities).
  + Food or color additives.
* 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. **IRB PACKETS MAY BE REJECTED FOR NOT PROVIDING STUDY MEASURES.** For example, you should not just say you are measuring stress, but instead say you are measuring stress using the written form of Cohen’s Perceived Stress Scale.
* Any statistical methods used should be included here.
* If you have more than one study session or visit, you may include a schedule of assessments chart to illustrate which procedures occur at a visit.

Example Schedule of Assessments

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Visit 1 | Visit 2 | Visit 3 | Follow-up phone call |
| Medical History | X |  |  |  |
| Questionnaire #1 | X | X | X | X |
| Blood Draw |  | X |  |  |
| Questionnaire #2 |  | X | X |  |

**RISKS & BENEFITS**

* All reasonably foreseeable risks or discomforts must be described in the protocol (or other protocol materials, e.g., Investigator’s brochure) and the Consent Form. Risks and discomforts should be classified as common, uncommon, or unlikely/rare).
  + Include all non-medical risks – psychological, legal, social, financial/economic, etc.
  + Include all medical risks, such as:
    - Complications of surgical and non-surgical procedures.
    - Drug side effects and toxicities.
    - Device complications/malfunctions.
    - Radiation risks.
  + If it is reasonably possible that a previously unknown condition (an incidental finding) could be discovered about the subject (e.g., disease, mental health, thoughts of harm to self or others, genetic predisposition, etc.), describe how this will be handled.
  + Indicate if any medical or psychological resources are available to participants.
* Benefits \*Compensation/gifts/reimbursements are not benefits.\*
  + Potential benefits to the individual participants.
  + Potential benefits to society.

**DATA SECURITY & PRIVACY/CONFIDENTIALITY**

* Describe the data and/or biological samples collection methodology (including who will perform what tasks and who will have access to the data).
* Describe data protection/security plans during all phases of the research. Specify formats (e.g., hardcopy, electronic file, etc.) and the location [PI office, computer (stand-alone or networked), secure server, mobile device (e.g., flash drive, external hard drive, tablet, etc.), cloud (specify service/vendor), etc.], and additional protections (password protection, encryption, anonymizing techniques, restricted access, confidentiality agreements, etc.).
* Describe recordkeeping and record retention plans. Specify the format (e.g., hardcopy, electronic file, password protection, encryption, etc.) and the location [PI office, computer (stand-alone or networked), secure server, mobile device (e.g., flash drive, external hard drive, tablet, etc.), cloud (specify service/vendor), etc.]. \*Remember that research records must be kept for at least 3 years from the completion of the study.\*

**DATA & SAFETY MONITORING**

* For studies that are minimal risk, describe how potential problems will be monitored and handled (e.g., breaches of confidentiality, emotional upset), including procedures for reporting deviations from the approved study plan and procedures for recording and reporting unanticipated problems and/or adverse events.
* For clinical studies or research involving more than minimal risk to subjects, describe:
  + Who will monitor adverse events (AEs) and unanticipated problems (UPs) involving risks to subjects or others and when events will be assessed.
  + How AEs or UPs will be recorded and communicated amongst research team members and who is responsible for making the reports.
  + If a Data Monitoring Committee (DMC) or a Data and Safety Monitoring Board (DSMB) has been formed for the study, describe the composition and how frequently it meets.
  + Identify how often AEs and UPs will be monitored and what events will be reported to the sponsor and/or the IRB.
  + Describe stopping rules for the study.
  + Describe what occurs if a subject withdraws prematurely.

**REFERENCES**

**APPENDICES**

* May include:
* Data collection forms, case report forms (CRFs).
* Study tools (e.g., questionnaires, surveys, instructions, etc.).