Preface

*This document describes the elements required for a simple minimal risk research protocol. Minimal risk studies may require more elements and oversight structure if the complexity or size of the study adds additional importance.*

*“****Minimal risk*** *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” See the Common Rule at* <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>*.*

*Further Guidance on what categories of research would meet minimal risk definition can be found at* <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm> *.*

*Minimal Risk studies, while simpler than studies of greater than minimal risk, still have regulatory obligations. A well written protocol is the prologue to well conducted research and as such, a minimal risk protocol should include, at a minimum, sections on brief background/rationale, study objectives, expected risks/benefits, eligibility, subject enrollment, study design/procedures, data collection and management, data analysis, quality control and quality assurance, statistical considerations, informed consent, privacy issues, unanticipated problems, and references. The following pages describe a template suitable for use. It is anticipated that the average minimal risk study can be described in less than 10 pages using this template. A few thoughtful sentences in each section are preferred to large chunks of information cut-and-pasted from other documents.*

*A grant application is not acceptable as a protocol.*

**Title**

(If not obvious from the protocol title, consider adding a subtitle that briefly summarizes the trial)

Principal Investigator:

(List Principal Investigator’s name, degree, position an affiliation)

**Funding Mechanism:** (e.g., grant or cooperative agreement #)

**Institution(s):**

**Other Identifying Numbers:** (e.g., Institution-assigned number, HUM

**Protocol Amendments:**

(Any modifications to the protocol should be annotated on the coversheet or in an appendix. The annotation should note the exact words that are changed, the location in the protocol the date the modification was approved, and the date it became effective.)

**Draft or Version Number: 0.x (for draft) or x.0 (for final)**

**Day Month Year:** (Write out the month and use international date format, e.g., 23 January 2008)

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Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations.

|  |  |  |  |
| --- | --- | --- | --- |
| Site Investigator:\* | | | |
| Signed: |  | Date: |  |
|  | Name Title |  |  |

\* The protocol should be signed by the clinical site investigator who is responsible for the day to day study implementation at his/her specific clinical site.

List of Abbreviations

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# 1 Background/Scientific Rationale

* *Describe the research problem and provide rationale for the research.*
* *Briefly summarize prior experience and/or history relevant to the research.*
* *Discuss briefly any literature important to the study and include references in Section 12.*

# 2 Objectives

* *Specify objectives or specific aims.*

# 3 Expected Risks/Benefits

* *Include expected risks and benefits to subjects and/or society.*

***NOTE****: This information will be used to determine whether an event is “Expected” and therefore not an unanticipated problem requiring expedited reporting.*

# 4 Eligibility

* *Identify the subject/donor population being evaluated by the protocol.*
* *List inclusion and exclusion criteria.*
* *Indicate the source of subjects/donors.*
* *Describe specifically and state the justification for any vulnerable population or any excluded populations, for example: minors.*

# 5 Subject Enrollment

* *Describe screening and enrollment.*
* *Describe from where subjects will be recruited and any advertising or recruitment materials that will be used.*
* *Describe what happens with screen failures and any data obtained from screen failures.*

# 6 Study Design and Procedures

* *Describe the study design. The description should be capable of meeting the study objectives.*
* *Provide a thorough description of all study procedures, assessments and subject activities in a logical and sequential format.*
* *Include the expected duration of the study and of subject participation.*
* *Consider including a flow diagram for clarity.*

*For particular types of studies, the following information should be considered and provided:*

**For Specimen Collection Studies**

* *Describe the specimens to be collected.*
* *Describe aliquoting and any plans for retention specimens.*
* *Describe tracking and labeling system.*
* *Describe where the specimens be stored and who will be responsible for care of specimens during storage.*
* *Describe how long the specimens will be kept.*
* *Describe how specimens will be destroyed at study completion.*
* *If specimens will be banked for future use, describe what the process is for providing investigators with access to the bank.*
* *Describe how such requests and access with be tracked.*
* *Describe how specimens will be analyzed (type and state of development of assay, controls, etc.)*

*Consent Considerations:*

* + *Informed consent must allow subjects to determine future use, other use beside specific research and use for genomic projects.*
  + *Provisions must be made to allow for withdrawal of a specimen if a subject withdraws consent and link is still maintained.*

**Behavioral Intervention Studies**

* *Describe how the behavioral intervention will be developed or adapted for use.*
* *Describe how fidelity of the intervention process will be assured.*
* *Describe how competence or compliance with fidelity will be demonstrated.*
* *Describe how fidelity and competence will be maintained and demonstrated throughout the study.*
* *Describe how compliance with intervention will be ascertained.*
* *Describe what will be done with any audio or video tapes after the study is completed.*

*Consent Considerations:*

* + *Describe in the informed consent what will be done with any audio, image, video or digital records after the study is completed*

**For Studies that Collect Existing or Prospective Data**

* *Describe the source of the information.*
* *Describe whether data are to be collected prospectively (come into existence after the award).*
* *Describe whether data are collected retrospectively (exist at the time of the award).*
* *Describe the time period of the medical information under review.*
* *Describe who will have access to collected information.*
* *Describe how long will the information be kept.*
* *Describe plans for destroying the data or other handling once the study is completed.*
* *Describe any plans for de-linking, coding, or de-identifying collected information.*

**Focus Group Requirements**

* *Describe qualifications of facilitator or individual supervising facilitation. Expectations include:*
  + - *Prior experience facilitating groups*
    - *Adequate knowledge of the topic*
    - *Understands the purpose of group*
* *Provide script or discussion questions that will be used in focus group.*
* *Describe any literacy or foreign language concerns or accommodations.*
* *Describe how information will be captured.*
* *Describe how information from focus group will be presented and used.*
* *How will focus group responses be summarized and integrated?*
* *How will contradictory responses be handled?*
* *Will there be thematic or qualitative coding of transcribed discussions?*
* *Will focus group responses be used to guide the development of education materials, measures, interventions or other research procedures, publication, or inform study design?*
* *Describe whether information drawn from focus group will be shared with group subjects.*
* *Describe what will be done with any audio, image, video or digital records after the study is completed.*

*Consent Considerations:*

* *Describe in informed consent what will be done with any audio, image, video or digital records after the study is completed.*

**Survey studies**

* *Describe interview methodology***.**
* *Describe development or selection of questionnaire****.***
* *Describe any literacy or foreign language concerns or accommodations.*
* *Indicate whether questionnaire is validated****.***
* *Describe how questionnaire will be tested (e.g., piloted)****.***
* *Describe how missing or incomplete information will be handled in analysis****.***

**Studies involving use of product (licensed, labeled of small size, simple)**

* *Name and description of product.*
* *Route of administration, dosing, dosage regimen and duration.*
* *Describe how compliance with product will be ascertained.*
* *Include information on how product will be obtained, stored, and tracked.*
* *Describe how any adverse events or serious adverse events will be handled.*
* *Attach product label as an Appendix to the protocol. The adverse events will describe expected adverse events.*

# 7 Data Collection and Management Procedures

* *Outline the process for data procurement.*
* *Describe source documents and how data will be collected from source documents and incorporated into the database.*
* *Describe who will have access to the data and how data will be maintained in a secure manner.*

# 8 Data Analysis

* Describe arrangements for data analysis.

# 9 Quality Control and Quality Assurance

* Describe how data will be evaluated for adherence with the protocol and for accuracy in relation to source documents.
* Describe who is responsible for the evaluation of data quality and how frequently this will be done. A reference to site or institutional SOPs can fulfill this item.

# 10 Statistical Considerations

* If a study incorporates qualitative rather than quantitative methods, indicate this and describe qualitative analysis and disregard the rest of this section.
* Describe how the data will be examined and statistically analyzed to answer the objectives.
* Provide a brief sample size calculation or description of sample size calculation. Include methods and assumptions such as loss to follow-up, as appropriate.

# 11 Regulatory Requirements

11.1 Informed Consent [[1]](#footnote-1)

* *Describe how informed consent will be obtained and who will obtain it.*
* *If research involves minors, describe assent process, as applicable.*
  + *Written in layman’s language understandable to the people being asked to participate.*
  + *A statement that the study involves research.*
  + *An explanation of the purposes of the research.*
  + *The expected duration of the subject’s participation.*
  + *A description of the procedures to be followed.*
  + *Identification of any procedures which are experimental.*
  + *A description of any reasonably foreseeable risks or discomforts. If there are none, this should be stated.*
  + *A description of any benefits to the subject or to others that may reasonably be expected from the research. If there are none, this should be stated.*
  + *A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.*
  + *An explanation of whom to contact for answers to pertinent questions about the research and the research subjects’ rights, and whom to contact in the event of research-related injury to the subject.*
  + *A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.*
* *Possibly applicable*
  + *A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*
* *Additional elements, as appropriate:*
  + *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
  + *Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.*
  + *Any additional costs to the subject that may result from participation in the research.*
  + *The consequences of the subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
  + *A statement that significant new findings developed during the course of the research, which may relate to the subject’s willingness to continue participation, will be provided to the subject.*
  + *The approximate number of study participants*

## 11.2 Subject Confidentiality

* *Describe how the subject’s confidentiality will be maintained.*
* *Describe who will have access to the data.*
* *Provide justification for use of personally identifiable data or private health information (PHI).*
* *Describe whether a Certificate of Confidentiality will be required. See* <http://grants.nih.gov/grants/policy/coc/appl_extramural.htm>.

## 11.3 Unanticipated Problems[[2]](#footnote-2)

* *Describe process for reporting any unanticipated problems to IRB*
* *See* <http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm>.

# 12 References

* *Cite supporting material organized in a standardized bibliographical manner.*

Appendices

Other Documents

* CRF copies
* Quality Management Plan
* Data Management Plan

1. The IRB may waive some or all elements of informed consent – consult the IRB for consenting requirements. [↑](#footnote-ref-1)
2. The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

   * unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
   * related or possibly related to participation in the research (in the guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
   * suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

   An incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in order to protect the safety, welfare, or rights of subjects or others. [↑](#footnote-ref-2)