Guidance for Investigators: Writing a Research Protocol

This guidance is offered to assist investigators in drafting sound protocols for applications to OSF Research Administration and/or submissions to the IRB of record. Each of the topics that apply to the planned research should be addressed in the final protocol document. There is no required protocol format or template; different sections and formatting may be used, provided the necessary study plan information is included.

General Info (Typically located on protocol cover page)

- Title – Specify the official protocol title. Also include an abbreviated title and/or acronym if they will be used.
- Study Sponsor and Monitor – Provide the names of the individuals or entities sponsoring and monitoring the study.
- Principal Investigator – Provide name, credentials and contact information.
- Location – Provide the name, address and contact info for the primary location where the research will be conducted.
- Protocol Identification and Version Control – Provide a unique identifier for the protocol ("protocol number"), as well as a control number or date to facilitate study-specific communication and to distinguish between multiple protocol versions resulting from changes.
- Section and Page Numbering System – Number the protocol sections and pages to facilitate study-specific communication.

Background

- Name and describe all investigational products (i.e. drugs/biologics/devices) and procedures.
    - When relevant, include description and justification for route of administration, dosage, regimen, and treatment periods.
- Name and describe alternative treatments that are available.
- Describe previous relevant studies and provide a summary of their findings.

Objectives

- State the purpose of the research, including any hypotheses being tested.
- Describe the primary and secondary aims of the research, and include the rationale for the outcome measures that were selected.

Study Methods

- Research Design – Describe the type of research proposed (e.g. experimental, observational, survey) and specific study design that will be used (e.g. controlled trial, randomized, blinded, prospective, retrospective).
- Study Population – Describe how research participants will be identified, recruited and selected (i.e. inclusion/exclusion criteria).
    - If vulnerable populations will be included in the research, describe the additional protections in place to protect them.
    - Specify the number of participants needed (sample size) for the planned statistical analyses.
    - Describe the compensation for participation that will be offered, including plans for prorating compensation for participants that do not complete the research.
- Study Procedures – Provide a study visit-by-visit list or table of procedures that will be done on participants, including the expected total duration of study participation.
- Data Collection & Monitoring – Describe how the data will be collected and what tools will be used to capture and store it. Outline the plan for monitoring the data throughout the study for accuracy.
- Informed Consent – Describe the informed consent process that will be used to enroll participants.

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Risk/Safety

- Describe the expected risks of study related procedures and treatments that are not standard of care, and how those risks are minimized by the study design.
- Provide the plan for safety monitoring and reporting of adverse events, serious adverse events and unanticipated problems involving risks to participants or others.
- Provide the investigator's risk/benefit assessment of the research for participants and others impacted by the research.
- Describe the potential study-related costs to participants, including the plans for handling compensation for injury resulting from research participation.

Privacy & Confidentiality

- Describe how the privacy of participants will be maintained, including a statement that if any results of the research are published, the identity of participants will not be included.
- Describe how the confidentiality of research records that identify participants will be maintained.

Oversight & Ethics

- State the federal regulations and local laws that apply to the research.
- Specify that the research plan will undergo IRB review and receive approval prior to initiating the research or any subsequent changes to the research plan.
- Describe the general monitoring plan for the research, including who will monitor the research and when.
- State that the research records will be made available for monitoring, auditing, IRB review and regulatory inspection by providing direct access to study source data.
- Describe the conditions under which the research may be prematurely terminated, and who will be responsible for making this determination.

Data Use & Management

- State the intended use of the research data, including plans for dissemination of findings and publication.
- Describe the statistical analyses that will be conducted in the research data.
- Detail the research data storage plan, including how, where, security measures, etc.

References

- Include a list of references used throughout the research protocol.

Appendices

- Include additional relevant research materials referenced in the research protocol, such as surveys, questionnaires, rating scales, etc.