**ESPU Research Committee Protocol Template**

This template should be used for studies which do not involve new investigative drugs or devices which involve a randomized clinical trial. These types of studies require an expanded protocol with additional detail such as dosing, reporting of adverse events, etc.

This template is applicable to most studies, including observational studies, pre/post-intervention studies, case/control studies, biological sample collection, qualitative studies, cross-sectional studies, and studies that randomized into standard of care treatment.

The purpose of this protocol template is to assist you in addressing all aspects of study design. Not all of the questions listed below may apply to your specific study. Skip the ones that are not applicable.

Instructions and examples are listed in each section of the protocol in red.

The goal of a protocol is to provide enough detail that anyone can read your protocol and duplicate your study. If your protocol is written appropriately, you should be able to copy/paste into the background and methods section of a manuscript without having to add additional details.

<PROJECT TITLE>

<Date>

PRINCIPAL INVESTIGATOR:

DEPARTMENT:

INSTITUTION:

PHONE:

EMAIL:

CO-INVESTIGATOR: CO-INVESTIGATOR:

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STUDY COORDINATOR: RESEARCH ASSISTANT:

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**Background/Introduction**

This section should resemble the introduction/background section to a manuscript. Areas you should address:

1. Has this subject matter been previously published, and if so, at what evidence level (i.e. what was the study design and sample size? Single or multiple center?) Include citations;
2. Given current knowledge on the subject, how will the proposed study add to the literature (i.e. what is the knowledge gap and how will this study fill it?);
3. What is the potential impact of the proposed study (i.e. how will it change current practice?).
4. If you’ve collected preliminary data, provide details and results.

Research Question

What is the question this study will be answering? Be very specific with your language, as this question will guide the rest of the language used in your study.

Primary and Secondary Aims

Given the study question, provide your primary aim (may be the same as the study question) and secondary aims if applicable. Provide hypotheses for any aims which involve a comparison between two or more groups.

Outcome Definitions/Data Points Collected

Define all of your outcomes that will be reported and/or compared. Be very specific. This section can also be in a table format for clarity.

Study Design

State your study design (i.e. case report, systematic review, retrospective case series, retrospective case control, prospective cohort, prospective case control, cross-sectional/survey). Use descriptive words such as pilot study, single center, multiple center, descriptive study, etc. as well.

Target Population

Describe the population that will be represented by your study.

Inclusion/Exclusion Criteria

List essential requirements for all groups in the study.

If case/control study, list criteria for cases and controls separately.

Carefully consider potential demographic or health characteristics/conditions which may introduce bias or confounding. When comparing between two or more groups, the groups should be as equal as possible in all other aspects except outcomes. If you are performing a retrospective review or a survey, you should consider listing a threshold for missing data in order to be included in the study (i.e. respondents must answer 95% of the survey questions to be included).

Sampling Method/Recruitment Process

How will you recruit for this study? Bias can easily be introduced in this step, so think of your target population, and plan carefully.

For example, if you are conducting a survey on social media practices, a landline phone survey would not be very representative of people who use social media since many people don’t have land lines, and those that do have caller ID. This method will most likely result in a sample of older people who may/may not use social media.

This section should include details such as:

* How/where will you identify potential subjects?
* If your study is retrospective, how will you identify charts for review?
* If your study is prospective, will you advertise the study?
* How do the people identifying these subjects have access to the population?
* What is your sampling method? (an internet search on “Khan Academy sampling methods” will assist you with different types)
* Who will approach people to see if they are interested in participating?
* Where will they be approached (keep in mind need for privacy)?
* Who will make sure potential subjects meet the inclusion/exclusion criteria (screening)?
* Will you track people who decline to participate in order to identify a selection bias?

Study Retention/Withdrawal

If a prospective study, who/how will subjects be tracked to minimize loss to follow-up? What will happen to any data or biological samples if a subject chooses to withdrawal from the study?

Study Procedures

These details are very important in a study as there is potential for introduction of various bias. It will also help you determine if a study is feasible. The best way to write this section is to imagine step-by-step what will occur to a chart/patient/biological sample once entered/enrolled into the study. Provide details for such things as:

1. What procedures will chart/patient/biological samples be exposed to? Provide details for all procedures. For example:
   1. If diagnostic testing will occur, describe the test and how the results are measured. How are the results reported and how will they be used in your outcomes? Is the sensitivity/specificity known?
   2. If a survey is used, describe the survey. How was it developed or is it an existing, validated survey? How is it scored?
   3. If a biological sample, describe what laboratory experiments they will be subjected to and the experiment protocol(s).
   4. Consider creating a study timeline detailing when study activities will occur. This is very helpful in planning your study and ensuring all study personnel have a clear understanding of study procedures.
2. Where will data be collected? (i.e. During the clinic visit, survey will be given in the clinic waiting room, etc.)
3. How often will data be collected? (i.e. every visit; baseline and last followup visit, etc.)
4. Who will collect the data? Do they have the knowledge to collect this data or do they need training? Do they have time to collect this data?
5. How will data be collected and entered (i.e. on paper then entered into an Excel spreadsheet, etc.)? Remember, the more steps in the data collection process, the more opportunity to have data entry error occur. Who will enter the data? Will they have time to enter the data?
6. What will you do to check data quality? Data error is a fact of life, and will exist in your study. Depending on how much error is in your data, you could reach false conclusions. Make a plan to minimize data entry error, and check for data quality in various phases of your study (i.e. If more than one person will be collecting/entering data, how will inter-rater reliability be tested/ensured?)
7. How/where will the data be stored, and who will have access? Keep in mind privacy issues and the need to store data in a secure fashion.

Sample Size Justification

If your study is comparative, how many subjects are required in each group? In order to calculate sample size, you will need to know the distribution of the outcome being compared, and the minimum (clinical) effect size.

If your study is not comparative, state that your study is descriptive only and therefore no sample size calculation was performed.

Feasibility, Accrual, and Expected Duration of Accrual

How long do you expect it will take to accrue your sample size? If the study is complicated, it is advisable to add a study timeline figure.

Example: Approximately 300 patients with this condition are seen in our clinic annually. We estimate 10% will decline to participate (n=30), and 3% (n=8) will be lost to follow-up. Therefore, we anticipate it will take six months to accrue our required 130 subjects.

Study Limitations

No study is perfect. What are the limitations of your study? For example, your study population may not be representative of the general population, referral/selection bias may impact your results, or your sample size may be limited. Think critically about the population your study represents and your study procedures.

Data Analysis

Provide a statistical plan for each specific aim. Methods should be written for each hypothesis.

Administrative Organization/Roles and Responsibilities

Describe the participating units, including other participating study sites, laboratories, telephone call center, data management center, and coordinating center as applicable. List study personnel and their responsibilities.

Use of Study Results

How will the results be used? Will they be used to inform an intervention? A prospective randomized study? To seek grant funding? In a presentation/publication?

Study Budget

If your study involves any procedures that are outside standard of care (therefore are not covered by insurance), provide details on how you will pay for these procedures. Remember to consider cost for personnel time as well.

References Cited

Provide the citations for all publications referenced in the text.

Appendices

Include data collection forms, surveys, recruitment materials, etc.