**Template for Outlining a Study Proposal or Writing up the Results\***

\*Structure adapted from *Annals of Emergency Medicine*, <https://www.annemergmed.com/content/structured>

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**Before You Begin**

There are lots of good web-based resources you can use to plan and write-up your research and scholarly activity. Below are a few of the better resources:

Equator Network

<https://www.equator-network.org/toolkits/>

SAEM Reason for Research

<https://www.saem.org/detail-pages/publication/reason-for-research>

SAEM Grants Guide

<https://www.saem.org/research/apply-for-a-grant/saem-grants-guide>

ACEP article on taking an abstract to manuscript:

<https://www.acep.org/how-we-serve/sections/emergency-medicine-research/news/september-2015/scientific-writing-taking-an-abstract-to-manuscript/>

Annals of Emergency Medicine guidelines and preferences for specific research study designs <https://www.annemergmed.com/content/designs#chart>

Elsevier Research Academy

<https://researcheracademy.elsevier.com/>

Bebarta & Cairns (Eds): Emergency Care Research: A Primer. <https://www.emfoundation.org/globalassets/general/pdfs/acep-research-primer-book-pdf.pdf>

**Introduction Subheadings**

Keep the introduction brief - 500 words or so. Concisely argue how the topic is new, scientifically important, and clinically relevant. All but the shortest introductions will benefit from separation into three sub-headers:

* **Background:** Describe the circumstances or historical context that set the stage and led you to investigate the issue. This is where the literature search should be synthesized and presented.
* **Importance:** Describe why your investigation is consequential. What are its potential implications? How does it relate to issues raised in the first paragraph? Why is this specific investigation the next logical step?
* **Goals of This Investigation:** Clearly state the specific research objective or hypothesis and your primary outcome measure.

Note: for novel studies or those that are more involved, a longer, more detailed introduction is often necessary. Describe the theoretical foundations of the topic, and carefully review the most relevant data to date. Be sure to highlight the gaps in knowledge that you are filling.

**Methods Subheadings**

The Methods section should be organized with logical and sequential subheadings. The optimal subheading choices will vary with the analysis, but the following examples are applicable to most clinical research:

* **Study design and setting:** Describe the study design using standard terms and descriptions. and describe the study setting in a fashion that conveys characteristics that could affect the external validity (generalizability) of the findings.
	+ Be certain to visit the *Equator Network* and locate your study design and check out the guidelines you should be following: <https://www.equator-network.org/>.
	+ For *retrospective chart reviews*,check out <https://els-jbs-prod-cdn.jbs.elsevierhealth.com/pb/assets/raw/Health%20Advance/journals/ymem/kaji.pdf>.
* **Selection of Participants:** Describe how participants were identified, screened, and enrolled. Remember to consider all participants including patients, providers, and outcome assessors, as appropriate. Describe specific inclusion and exclusion criteria.
* **Interventions:** Describe interventions in sufficient detail to permit replication. Describe any blinding of subjects, providers, outcome assessors, or data analysts. Describe methods for determining whether the intervention was actually received.
* **Measurements:** Discuss how and when measurements are made. Discuss the precision and reliability of the measurements. How were spurious or missing measurements handled? Discuss who collected the data and how they collected it. Discuss how data were entered, checked, and processed. For some studies these details might be best provided in the Interventions or Outcomes subsections.
* **Outcomes:** Describe the study's primary and secondary outcome measures, and if needed explain why they were chosen to address the study objective. When possible, use outcomes that have been previously validated, or provide evidence of your own efforts to validate the measure. Emphasize patient-centered outcomes (e.g., pain, days off from work, death) over intermediate outcomes (e.g., change in forced expiratory volume, change in asthma score).
* **Analysis:** Detail the primary analysis and specify any software that was used, including the name of the software and the company that produces it. Provide references for any non-routine analytic methods. If appropriate, detail [sensitivity analyses](https://www.annemergmed.com/content/methstats-sensitivity_analyses) that explore how results change when assumptions about the investigation are modified.
* **Benefits & Risks:** List the potential benefits of the study to the participants themselves, such as increased monitoring, or perhaps the chance to receive a novel intervention. If no benefits (which is not uncommon), then state “none.” As for risks, virtually all studies have some, such as loss of privacy if the data is compromised. interventional studies pose greater risks, and these should be listed along with any factors that will mitigate the risks.
* **Ethics:** If the study involves human or animal research, to include chart review studies and most database research, it likely will require ethics board approval. Human studies require IRB approval, animal studies IACUC approval. Describe, as appropriate, the methods of informed consent and privacy protection (HIPAA).

If you feel the study will be exempt or expedited category of IRB approval, list the justifications. In many cases studies are submitted to the institution to officially determine that it is not human or animal research and thus not covered by the ethics boards. The department research coordinator can assist with this.

**Results Subheadings**

Skip this section if you are writing up a proposal. For completed research, this section is mandatory.

The Results section should be organized with logical and sequential subheadings. The optimal subheading choices will vary with the analysis, but the following examples are applicable to most clinical research:

* **Characteristics of study subjects:** Account for all subjects, beginning with the number of subjects who could have participated in the study.
* **Main results:** Present the results in a logical, sequential order that parallels the organization of the Methods section. Present as much data as possible at the level of the unit of analysis, graphically if possible. Emphasize the magnitude of findings over test statistics, ideally using [size of effect](https://www.annemergmed.com/content/methstats-size_of_effect) and associated confidence intervals for each outcome. Describe sensitivity analyses if appropriate.

**Limitations**

This section is important for both research proposals and completed studies.

Explicitly discuss the limitations of your study, including threats to the internal and external validity of your results. When possible, examine the magnitude and direction of each bias and how it might affect the interpretation of results.

**Discussion**

This section is generally skipped in research proposals although it is optionally used as needed. It is mandatory for completed research projects.

Briefly summarize the results and how they relate to your area of investigation. Consider only those published articles directly relevant to interpreting your results and placing them in context. Do not stress statistical significance over clinical importance. Avoid extrapolation to populations or conditions that you have not explicitly studied in your investigation. Avoid claims about cost or economic benefit unless a formal cost-effectiveness analysis was presented in the Methods and Results sections. Do not suggest "more research is needed" without stating what the specific next step is.

Optionally, you may also include a paragraph "In retrospect, . . ." to candidly discuss what you would do differently if given the opportunity to repeat the study, so others can learn from your experience.

**Conclusion**

Omit this section for research proposals.

Take care that the conclusion is restricted to what can be justified by your experimental results. That is, a clear line should connect the methods section (what you measured), the results, and the conclusion.

**Additional Info for Proposals:**

**Budget**

For early phase proposals, this can be rough, back-of-envelope estimates. For late phase proposal you will want to meet with a grants specialist to work out a budget that meets institutional requirements.

Minimum budget sections:

* Personnel
	+ Faculty: List every faculty member involved in the project. Describe an estimate of the principal investigator and associate investigator(s) time spent on the study expressed as a *percent effort x number of months the study will run x base salary*. Small studies have a % effort typically ranging from 0 (no salary support) to 5%. Larger grant-funded studies may have values 5%-20% or more depending on the scope.
	+ Staff: Research assistants (RA), study coordination, etc, must be considered. No need to list individuals by name, just the job duty. Nominal values range from 0-5% for small studies to 100% or more for large studies utilizing lots of RA time.
	+ Trainees: Estimate the trainee (resident, fellow, student) time. Nominal values range from 5-10%. In most cases trainees may commit time but their line-item budget is zero as their salary is already included in their training program.
* Supplies – these are disposable and consumable items.
* Equipment – this durable material, generally with a list price over $1k.
* Travel – list any travel costs associated with the study, such as a requirement to travel off site to conduct the study. Don’t include conference presentation travel right now as that depends on the specific grant rules.
* Miscellaneous – this category might include payments to participants (incentives to enroll), specific service contracts like laboratory support, or other items not included above.

**Execution Plan**

Depending on the complexity of the proposal, this section may be omitted or might require detailed explanation. Include the who/what/where/when/how details:

* Who: Collaborating departments, agencies, etc.
* What: Grant or funding source you are planning to seek.
* Where: The specific site(s) of the study.
* When: Rough timeline.
* Why: Explain nonintuitive parts of your execution plan so others can follow.
* How: Details of executing the study. For example, how the study will integrate with the ED or other clinical site.

*Good luck and remember that the DEM Research Support Team is there to assist you!*