

- 1) Title of your research project
- 2) Abstract
 - a) Give a summary of the research project (about 250 words)
- 3) Investigators
 - a) Include the name of the principal investigator and the names anyone else who will be involved in the research project
- 4) Objectives
 - a) State the hypotheses to be tested, this is the main question that your research tries to tackle
 - i) use the PICOT method to develop your hypothesis
 - (1) P (population)- what is your population of interest?
 - (2) I (intervention)- what intervention are you research projecting?
 - (3) C (comparison)- what groups are you comparing with your research project?
 - (4) O (outcome)- what is the outcome from therapy?
 - (5) T (time)- what is the time it takes to demonstrate an outcome?
 - ii) An example of a PICOT method hypothesis could be, “In males 65 and older with systolic heart failure, providing these patients with education on the benefit of aerobic exercise decreases readmission rates to the hospital over the next five years.”
 - b) Give the purpose for conducting the research project
- 5) Background Information
 - a) Detail any previous research done on the topic and explain what information is missing from the prior research
 - b) Describe any relevant preliminary data that you have collected
 - c) Describe how this research fills the gap in the current knowledge
- 6) Resources and Setting
 - a) Describe where the research project will take place
- 7) Methods
 - a) Recruitment
 - i) Give an approximation of how many subjects will be needed
 - ii) Describe in detail how subjects will be recruited to enroll in the research project
 - iii) Include the specific date range that subjects will be recruited
 - b) Inclusion and Exclusion Criteria
 - i) Describe the criteria you will use to determine which subjects will be included or excluded from the research project. Include as many details as possible including: age, specific conditions, etc.

- c) Time
 - i) Give the duration anticipated for the research project
 - ii) Provide an estimated date at which the research project will be complete
- d) Procedure
 - i) Give a step by step description of what your subjects will be asked to do in your research project
- e) Data
 - i) Explain what variables are being measured and what variables will be recorded
 - ii) If possible, describe how you will record the data, both the procedure you will use and the tools you will use (such as a spreadsheet)
 - iii) Describe a procedure for data collection and recording in a way that minimizes the spread of confidential patient information (in your data spreadsheet there should be no info to identify a patient)
 - iv) Consider using temporary identifiers, codes, or links between the subject's identity and the data being recorded. If you do this, please describe how it will be done.
 - v) Describe how the data will be analyzed

8) Confidentiality

- i) Describe whether the research project will use or disclose subjects' Protected Health Information (PHI).
- ii) If your research project includes PHI, describe how this identifying information will be secured (password protected, encrypted, limited access, etc.)
- iii) Keep in mind that the less PHI used in the research project, the more likely it is to get IRB approval. Make every attempt to limit the amount of PHI and limit the number or researchers who have access to it

9) Informed Consent

- a) Explain your procedures to get informed consent from the research subjects
- b) Include a copy of your informed consent form

10) Risks

- a) Explain any foreseeable risks to a patient enrolling in the research project
 - i) Include both short term and long term risks
 - ii) Make an effort to minimize risk whenever possible

11) Benefits

- a) List any potential benefits of the research project both to the patient and society in general

12) Special Considerations

- a) Explain whether or not your research will contain data of children, pregnant women, or prisoners. If they are included, explain why it is necessary to do so