Wayne State University
Institutional Review Board (IRB)

WSU IRB Administration Office
87 East Canfield, Second Floor
Detroit, MI, 48201
313-577-1628
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# What to Include in a Research Proposal

## When Submitting for IRB review

Most formats for research proposals, theses, dissertations or grant submissions will be accepted. However, please do not submit lengthy documents. If you do not already have a short written proposal, or if you need submit an abbreviated version of a dissertation, use the following elements as a guide to what information should be included in the research proposal submitted to the IRB. The proposal should accompany the completed IRB form(s).

### Background

Provide a section describing the rationale for the study. This section may include information from a literature review that provides a foundation for proposing the study.

### Objectives/Aims

Provide an explanation of the purpose(s) for conducting the study. Depending on the nature of the research, this section may include what research question(s) the study will attempt to answer; or a description of what be evaluated or tested in the research. List the study aims.

### Participant Population/ Data Characteristics

Provide a description of the anticipated research participants and/or a description of the data that will be collected in the research. Describe the Inclusion Criteria (criteria that must be met to be included) and Exclusion Criteria (criteria that if met will be excluded).

### Methodology

Provide a description of how the study will be conducted; a description of the data collection methods and tools; and a plan for data analysis. The plan for data analysis should include a description of how many participants/records/specimens are needed based on a statistical rationale for the effect/size (e.g., power calculation); any intended statistical plan based on the primary and secondary objectives of the study; and any literature citations supporting the methodology.

A description of a Data and Safety Monitoring Plan may be required if there are risks such as: potential to be harmed; a blinded study with a high risk intervention; a study population that has a high morbidity and mortality rate which may mask safety concerns with the study; or if only a few participants will be enrolled by one PI in a multi-site study. Data and safety monitoring is typically more applicable for medical research with an intervention but may also be required for behavioral research.

### Reference List

Provide citations for any literature or publications used for the proposal.