
In this module you will be provided with guidelines for ensuring the methodological soundness of a proposed research design.

The definition of and guidelines for methodological soundness, both of which will be addressed in this module, can also be found in 3 separate documents, namely, the “IRB Submission Checklist for Prospective Research Investigators,” the “IRB Tip Sheet – Guidelines for Faculty Sponsors of Student Theses,” and its companion, “IRB Tip Sheet – Guidelines for Planning Student Theses” that are found on the IRB web site, Technical Assistance area.

Audio is included in this presentation so please be sure your speakers are turned up on your computer. Click the forward button at the bottom of the window to advance to the next slide.
Specifically in this module you will be provided with:

- The definition of “methodological soundness” and,
- Guidelines for “methodological soundness”.

Module IV - Overview

- Definition of “methodological soundness”
- Guidelines for “methodological soundness”
Investigators often ask, “What is methodological soundness?”

In short, and generally, speaking, methodological soundness refers to an indicator of quality in research. That is, when the methods used are able to answer the study question, a research proposal may be deemed “methodologically sound.”

Other indicators of quality research may include, but are not limited to, “ethical soundness” (i.e., when unnecessary harm to human subjects has been avoided or minimized and when the study has been carried out and reported honestly), “usefulness” (i.e., when the study contributes significantly to the scientific debate or knowledge on a subject), and “accuracy” (i.e., when the presented information is a true reflection of what went on in the study).
Methodological Soundness Guidelines

The guidelines for methodological soundness listed in this presentation are phrased as questions that can be asked by an investigator when self-assessing his/her research proposal prior to submission to the IRB.

As a reminder, the guidelines listed here are also addressed in three separate KU IRB documents, specifically, the “IRB Submission Checklist for Prospective Research Investigators,” the “IRB Tip Sheet - Guidelines for Faculty Sponsors of Student Theses,” and its companion, “IRB Tip Sheet - Guidelines for Planning Student Theses” found on the IRB web site Technical Assistance area.

1. Are the research methods clearly described, and are they appropriate to the research question(s)?
   Ensure that the research design is both described and appropriate to the research question(s).

2. Is there control for bias and/or possible confounding factors?
   Address/control for investigator bias and/or contributing factors (as applicable).

3. Do measurement techniques appear acceptably valid and reliable?
   Address the reliability and validity of any instruments used to collect data.

4. Is the design strong enough to permit generalization (if this is desired)?
   Qualify anticipated findings by addressing whether or not the research design is strong enough to permit generalization.
5. Are there potential problem areas in the research design and has thought been given to alternative tactics?
Acknowledgment potential problem areas in the research design and consider alternative tactics.

6. Is the type of analysis appropriate, given the purpose of the study?
Articulate a data analysis plan that is appropriate to the purpose of the study.

It's important to note, that answering questions aimed at assessing methodological soundness doesn’t just happen at the investigator-level, but also at the IRB-level. These questions of methodological soundness are the same questions that IRB members consider when reviewing research submissions. In addition, and though it is not listed here, in the conduct of their review, IRB members often also consider if the research investigators are qualified and competent to carry out the study as proposed.
Thank you for investing your time to learn about the Kaplan University IRB.