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Guidance Document	Research Protocols and Plans
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"A good protocol is evidence that you have clarified your research project to the point that when it comes to data collection and analysis, you are confident about the analysis you are going to do and the implications of this analysis on your research questions."
-Lancaster University, 2018

Research Protocols and Ethical Review

A critical component to **almost all types** of research is a protocol/research plan. Without one, research cannot be conducted in a predictable, organized fashion. A protocol/research plan establishes a research blueprint that specifies all aspects of a study's conduct, including pre-specifying the research question, hypotheses, outcomes, analysis plans, and duration of follow-up. Finally, the protocol/research plan allows amendments to be made in a tracked fashion.

While the Western Research Ethics Manager (WREM) application asks specific questions to assess regulatory and ethical considerations, a protocol/research plan provides the explicit details and context of the actual conduct of the study. The WREM application is insufficient to replace a stand-alone protocol.

As of January 1, 2020, all initial HSREB applications (delegated level 1 & 2 and full board) must include a protocol/research plan. NOTE: this policy is not applicable to applications submitted to the Non-Medical (NM) REB.

Protocol Content

A protocol, or "research plan" is a single document that describes, at minimum, the:

- Background
- Rationale
- Objectives
- Design
- Primary and Secondary Outcomes
- Methodology
- Statistical/Analysis considerations

Depending on the nature of the research, some research plans may not need all of these sections (but many protocols/research plans will require even more sections). The Health Sciences Research Ethics Board understands that different disciplines will have different customary approaches to writing protocols/research plans. However, the fundamentals of explaining the *who, what, when, where, and how* of a study still apply. A protocol/research plan should include sufficient detail for reproducibility and so that changes to the research plan via future amendments can be reflected.

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Benefits

Writing a fully conceptualized protocol/research plan *before* completing the WREM forms will lead to a more consistent application and provide reviewers with sufficient information to better understand the research being proposed.

A protocol/research plan may also serve as the basis for a student research proposal, grant application, or even publication such that there is much long-term value to the initial investment of time and thought. Requiring a researcher to commit to certain aspects of the research before the study begins also reduces the incidence of important biases (such as the selective reporting of outcomes).

Resources

The following resources all provide good guidance on how to write and format a protocol/research plan. Depending on the nature of the study, some content may or may not apply at the discretion of the researcher.

1. The World Health Organization – Recommended format for a Clinical Research Protocol
   https://www.who.int/rpc/research_ethics/format_rp/en/
2. SPIRIT 2013 Statement – Website and Checklist
   http://www.spirit-statement.org/
3. National Institutes of Health – Website and protocol templates (Phase 2&3 IND/IDE clinical trials and for Behavioral and Social Sciences Research)
   https://grants.nih.gov/policy/clinical-trials/protocol-template.htm