Selecting a Research Topic

Carol Ott, PharmD, MPH, BCPP
Clinical Professor of Pharmacy Practice, Purdue University
Clinical Pharmacy Specialist, Psychiatry & Gender Health, Eskenazi Health
Indianapolis, IN

Disclosures

- Dr. Ott does not have financial or other relationships to disclose in relation to this presentation
- This presentation will not include discussion of off-label, experimental, and /or investigational use of drugs or devices

Learning Objectives

1. Choose an appropriate research topic for grant application
2. Discuss the importance of a clear research study purpose with supporting background information
3. Understand reasons for IRB approval
4. State the three types of IRB approval

Research Study Purpose

- A research study should have a purpose that explores new areas of health care, describes how a process is performed, and explains health care outcomes with a goal of improving overall health care and adding to the evidence base

- A purpose statement is formatted in one clear sentence that reflects the research question and research design and includes a broad statement of how the question impacts patient care, relating clearly to the research problem:
  - Example: The purpose of this retrospective chart review study was to determine the extent to which pharmacist intervention to switch oral antipsychotics to long-acting antipsychotics decreased the use of acute care services.

https://app.nova.edu/toolbox/Dissertation/Handouts/The%20Purpose%20Statement%20Handout%20Sep%2019%202012.pdf

Research Study Background

- The background section of a research study provides information about why the study is important
- Briefly cite important studies that support your research study
- Background sections can identify gaps in the evidence base that support the importance of your study
- Identified gaps should support the primary objective of your study (what you are studying) and/or the methods chosen for the study
- The background section in an abstract should include most important supporting information; save a longer background for the introduction section of a paper

https://www.enago.com/academy/what-is-background-in-a-research-paper/#:~:text=What%20is%20Background%20of%20the%20Study%20in%20Research,supports%20or%20refutes%20your%20thesis.

Why and When to Obtain IRB Approval

- Institutional Review Board (IRB) approval should be obtained when data will be collected and reported on that includes human participants
- The National Research Act established the requirement for IRBs in 1974 in response to human subject experiments that caused harm or did not ask for consent from participants
- Examples of studies that require IRB approval:
  - Research using human subjects data
  - Use of a non-public dataset with participant identifiers
  - Research projects collecting data that is anticipated to be included in a research presentation or paper

https://www.irb.purdue.edu/

Definition of Types of IRB Approval

Type of Review	Definition
Exempt	The study is determined to meet a minimal level of loss of privacy and includes educational/instructional activities, information that is collected from participants that can be completely de-identified, publicly available information, or collection of information that has already been obtained in the course of usual health care *(IRB submission should be completed and a decision of exempt by the IRB should be documented)*
Expedited	If an IRB submission is deemed to be non-exempt, it may be assigned to a subset of the IRB instead of the full board. This is usually done when the study has a risk of loss of privacy or the data is collected prospectively requiring informed consent from study participants
Full Board	If the risk to the study participant is considered to be greater than the risk of loss of privacy in everyday life, a full board review is required. This type of IRB review takes a longer period of time because the full board may meet monthly or less often

https://www.irb.purdue.edu/

Planning for IRB Approval

- Reviewing the website of the IRB that will be used is an important step in ensuring that IRB approval is built into the project timeline
- Exempt reviews may be completed in 1 – 2 weeks, expedited reviews in about 4 weeks, and full board reviews within 12 weeks
- The study CANNOT begin to recruit participants or begin data collection until the IRB approval is obtained
- Any recruitment or data collection prior to IRB approval must be excluded from the study data
- The research timeline submitted for grant applications must include IRB approval unless this has already been obtained prior to applying for the grant

Questions – Please email Dr. Ott at caott@iu.edu

Thank you for attending!

aapp FOUNDATION