

a study was submitted to the irb designed to evaluate

A Study Was Submitted to the IRB Designed to Evaluate: Methodologies and Approaches

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Introduction: Navigating the IRB Process for Research Evaluation

The phrase "a study was submitted to the IRB designed to evaluate" encapsulates a crucial step in the research lifecycle. Before any research involving human subjects can commence, it must undergo rigorous ethical review by an Institutional Review Board (IRB). This review process ensures that the study adheres to ethical principles, protects participant rights, and minimizes potential risks. This article explores various methodologies and approaches employed in studies submitted to the IRB, highlighting the diversity of research questions and the corresponding design choices. We will delve into the complexities of IRB review, the different types of research designs, data collection techniques, and ethical considerations involved.

1. Types of Studies Submitted for IRB Review: A Study Was Submitted to the IRB Designed to Evaluate... What?

A study submitted to the IRB can be designed to evaluate a wide range of phenomena. The specific methodology depends heavily on the research question. Some common types include:

Intervention Studies: These studies evaluate the effect of an intervention (e.g., a new drug, a therapy, an educational program) on a particular outcome. Examples include randomized controlled trials

(RCTs), quasi-experimental studies, and pre-post designs. A study was submitted to the IRB designed to evaluate the efficacy of a new medication for anxiety is an example of an intervention study.

Observational Studies: These studies observe and measure characteristics of a population without intervening. They can be further categorized into cohort studies (following a group over time), case-control studies (comparing individuals with and without a condition), and cross-sectional studies (measuring variables at a single point in time). A study was submitted to the IRB designed to evaluate the prevalence of smoking among adolescents is an example of an observational study.

Qualitative Studies: These studies focus on understanding the lived experiences, perspectives, and meanings associated with a phenomenon. Methodologies include interviews, focus groups, ethnography, and case studies. A study was submitted to the IRB designed to evaluate the experiences of cancer patients undergoing chemotherapy is an example of a qualitative study.

Mixed Methods Studies: These studies combine quantitative and qualitative approaches to provide a more comprehensive understanding of a research question. They often involve collecting both numerical and textual data and integrating the findings. A study was submitted to the IRB designed to evaluate the effectiveness of a new teaching method, using both standardized test scores (quantitative) and student interviews (qualitative) exemplifies a mixed methods approach.

2. Methodological Considerations: Designing a Study for IRB Approval

The design of a study is critical to its success and ethical conduct. Several key factors need to be considered when designing a study that will be submitted to the IRB:

Research Question: A clearly defined and focused research question is essential. It guides the selection of the appropriate methodology and data collection techniques.

Study Population: The study population must be clearly defined, including inclusion and exclusion criteria. This ensures that the study participants are appropriate for the research question and that the results are generalizable.

Sample Size: The sample size must be sufficient to detect a meaningful effect or answer the research question with adequate statistical power. This calculation often relies on statistical methods and prior research.

Data Collection Methods: The choice of data collection methods depends on the research question and the study design. These might include surveys, interviews, observations, physiological measurements, or administrative data.

Data Analysis Plan: A detailed data analysis plan should be developed before data collection begins. This plan specifies the statistical methods or qualitative analysis techniques that will be used.

3. Ethical Considerations in IRB Review: Protecting Participants

Ethical considerations are paramount in any research involving human subjects. The IRB meticulously

reviews studies to ensure that they adhere to ethical principles, such as:

Informed Consent: Participants must be fully informed about the study's purpose, procedures, risks, and benefits before they agree to participate. The informed consent process must be carefully documented.

Confidentiality and Anonymity: Participants' data must be protected from unauthorized access and disclosure. Techniques for ensuring confidentiality and anonymity should be incorporated into the study design.

Minimizing Risk: The study design should minimize the risks to participants, both physical and psychological. Any potential risks should be carefully weighed against the potential benefits of the research.

Vulnerable Populations: Special considerations are needed when conducting research with vulnerable populations, such as children, pregnant women, prisoners, or individuals with cognitive impairments. Additional safeguards may be required to ensure their protection.

4. The IRB Review Process: From Submission to Approval

Submitting a study to the IRB involves several steps:

1. Preparation of the IRB application: This involves completing all necessary forms and providing detailed information about the study design, methodology, risks and benefits, and participant protection measures.
1. IRB Review: The IRB reviews the application and may request clarifications or modifications before granting approval.
1. Approval or Rejection: The IRB either approves the study, requests modifications, or rejects the study.
1. Ongoing Monitoring: Even after approval, the IRB monitors the study's progress to ensure that it continues to adhere to ethical guidelines.

5. A Study Was Submitted to the IRB Designed to Evaluate: Examples Across Disciplines

The versatility of research methodologies means that "a study was submitted to the IRB designed to evaluate" can apply across a multitude of fields. Examples include:

Public Health: A study was submitted to the IRB designed to evaluate the effectiveness of a public health campaign aimed at reducing obesity rates.

Clinical Trials: A study was submitted to the IRB designed to evaluate the safety and efficacy of a new cancer treatment.

Social Sciences: A study was submitted to the IRB designed to evaluate the impact of social media on adolescent mental health.

Education: A study was submitted to the IRB designed to evaluate the effectiveness of a new teaching method.

Conclusion

The phrase "a study was submitted to the IRB designed to evaluate" underscores the critical role of ethical review in research. The design and methodology of any study involving human subjects must prioritize ethical considerations alongside scientific rigor. By carefully considering the research question, choosing appropriate methodologies, and adhering to ethical principles, researchers can ensure that their studies contribute to knowledge while protecting the rights and well-being of participants. The IRB process, though demanding, is crucial in ensuring the responsible conduct of research and the advancement of science ethically.

FAQs

1. What is an IRB? An Institutional Review Board (IRB) is an independent committee that reviews research proposals involving human subjects to ensure the protection of their rights and well-being.

1. Why is IRB approval necessary? IRB approval is necessary to ensure that research involving human subjects is conducted ethically and legally.

1. What types of studies require IRB approval? Most studies involving human subjects, including research, teaching, and training, require IRB approval.

1. What information is typically included in an IRB application? An IRB application includes details about the study's purpose, design, methodology, risks and benefits, participant recruitment, informed consent procedures, data management, and plans for data analysis.

1. How long does the IRB review process usually take? The IRB review process can take anywhere from a few weeks to several months, depending on the complexity of the study and the IRB's workload.
1. What happens if the IRB rejects a study? If the IRB rejects a study, researchers typically need to revise their proposal to address the concerns raised by the IRB before resubmitting it.
1. What are the common ethical principles considered by the IRB? Common ethical principles include respect for persons, beneficence, and justice.
1. Can a study be modified after IRB approval? Yes, but any significant changes to the study protocol usually require submitting an amendment to the IRB for review and approval.
1. What happens if an ethical violation occurs during a study? Any ethical violations must be immediately reported to the IRB, and appropriate corrective actions must be taken.

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Bankert, Bruce G. Gordon, Elisa A. Hurley, 2021-03-01 Institutional Review Board (IRB) members and oversight personnel face challenges with research involving new technology, management of big data, globalization of research, and more complex federal regulations. Institutional Review Board: Management and Function, Third Edition provides everything IRBs and administrators need to know about efficiently managing and effectively operating a modern and compliant system of protecting human research subjects. This trusted reference manual has been extensively updated to reflect the 2018 revisions to the Federal Policy for the Protection of Human Subjects (Common Rule). An essential resource for both seasoned and novice IRB administrators and members, Institutional Review Board: Management and Function provides comprehensive and understandable interpretations of the regulations, clear descriptions of the ethical principles on which the regulations are based, and practical step-by-step guidance for effectively implementing regulatory oversight.

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disadvantaged populations—racial minorities, women, people with mental illness, and people with communicable diseases such as HIV/AIDS, hepatitis C, and tuberculosis—are under correctional supervision. Because prisoners face restrictions on liberty and autonomy, have limited privacy, and often receive inadequate health care, they require specific protections when involved in research, particularly in today's correctional settings. Given these issues, the Department of Health and Human Services' Office for Human Research Protections commissioned the Institute of Medicine to review the ethical considerations regarding research involving prisoners. The resulting analysis contained in this book, *Ethical Considerations for Research Involving Prisoners*, emphasizes five broad actions to provide prisoners involved in research with critically important protections: • expand the definition of prisoner; • ensure universally and consistently applied standards of protection; • shift from a category-based to a risk-benefit approach to research review; • update the ethical framework to include collaborative responsibility; and • enhance systematic oversight of research involving prisoners.

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Regulation I. Glenn Cohen, Holly Fernandez Lynch, 2014-07-11 The current framework for the regulation of human subjects research emerged largely in reaction to the horrors of Nazi human experiment, revealed at the Nuremberg trials, and the Tuskegee syphilis study, conducted by US government researchers from 1932 to 1972. This framework combining elements of paternalism with efforts to preserve individual autonomy, has remained fundamentally unchanged for decades. Yet, as this book documents, it has significant flaws-including its potential to burden important research, overprotect some subjects and inadequately protect others, generate inconsistent results, and lag behind developments in how research is conducted. Invigorated by the US government's first steps toward change in over twenty years, Human Subjects Research Regulation brings together the leading thinkers in this field from ethics, law, medicine, and public policy to discuss how to make the system better. The result is a collection of novel ideas-some incremental, some radical - for the future of research oversight and human subject protection. After reviewing the history of US research regulations, the contributors consider such topics as risk-based regulation; research involving vulnerable populations (including military personnel, children, and prisoners); the relationships among subjects, investigators, sponsors, and institutional review boards; privacy; especially regarding biospecimens and tissue banking; and the possibility of fundamental paradigm shifts. Book jacket.

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Institute of Medicine, Board on Health Sciences Policy, Committee on Strategies for Responsible Sharing of Clinical Trial Data, 2015-04-20 Data sharing can accelerate new discoveries by avoiding duplicative trials, stimulating new ideas for research, and enabling the maximal scientific knowledge and benefits to be gained from the efforts of clinical trial participants and investigators. At the same time, sharing clinical trial data presents risks, burdens, and challenges. These include the need to protect the privacy and honor the consent of clinical trial participants; safeguard the legitimate economic interests of sponsors; and guard against invalid secondary analyses, which could undermine trust in clinical trials or otherwise harm public health. *Sharing Clinical Trial Data* presents activities and strategies for the responsible sharing of clinical trial data. With the goal of increasing scientific knowledge to lead to better therapies for patients, this book identifies guiding principles and makes recommendations to maximize the benefits and minimize risks. This report offers guidance on the types of clinical trial data available at different points in the process, the points in the process at which each type of data should be shared, methods for sharing data, what groups should have access to data, and future knowledge and infrastructure needs. Responsible sharing of clinical trial data will allow other investigators to replicate published findings and carry out additional analyses, strengthen the evidence base for regulatory and clinical decisions, and increase the scientific knowledge gained from investments by the funders of clinical trials. The recommendations of *Sharing Clinical Trial Data* will be useful both now and well into the future as improved sharing of data leads to a stronger evidence base for treatment. This book will be of interest to stakeholders across the spectrum of research-from funders, to researchers, to journals, to physicians, and ultimately, to patients.

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Digital Health Margo Edmunds, Christopher Hass, Erin Holve, 2019-01-17 This unique collection synthesizes insights and evidence from innovators in consumer informatics and highlights the technical, behavioral, social, and policy issues driving digital health today and in the foreseeable future. *Consumer Informatics and Digital Health* presents the fundamentals of mobile health, reviews the evidence for consumer technology as a driver of health behavior change, and examines user experience and real-world technology design challenges and successes. Additionally, it identifies key considerations for successfully engaging consumers in their own care, considers the ethics of using personal health information in research, and outlines implications for health system redesign. The editors' integrative systems approach heralds a future of technological advances tempered by best practices drawn from today's critical policy goals of patient engagement, community health promotion, and health equity. Here's the inside view of consumer health informatics and key digital fields that students and professionals will find inspiring, informative, and thought-provoking. Included among the topics: • Healthcare social media for consumer informatics • Understanding usability, accessibility, and human-centered design principles • Understanding the fundamentals of design for motivation and behavior change • Digital tools for parents: innovations in pediatric urgent care • Behavioral medicine and informatics in the cancer community • Content strategy: writing for health consumers on the web • Open science and the future of data analytics • Digital approaches to engage consumers in value-based purchasing *Consumer Informatics and Digital Health* takes an expansive view of the fields influencing consumer informatics and offers practical case-based guidance for a broad range of audiences, including students, educators, researchers, journalists, and policymakers interested in biomedical informatics, mobile health, information science, and population health. It has as much to offer readers in clinical fields such as medicine, nursing, and psychology as it does to those engaged in digital pursuits.

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of numerous physical disease states, as well as many cognitive-behavioral health disorders. This use of the term neurovisceral refers to the relationships between the nervous system and the viscera, providing a more focused and specific conceptual alternative to the now nearly archaic “mind-body” distinction. This awareness has led to the recent and growing use of HRV as a health biomarker or health status measure of neurovisceral functioning. It facilitates studying the complex two way interaction between the central nervous system and other key systems such as the cardiac, gastroenterological, pulmonary and immune systems. The utility of HRV as a broad spectrum health indicator with possible application both clinically and to population health has only begun to be explored. Interventions based on HRV have been demonstrated to be effective evidence-based interventions, with HRV biofeedback treatment for PTSD representing an empirically supported modality for this complex and highly visible affliction. As an integral measure of stress, HRV can be used to objectively assess the functioning of the central, enteric and cardiac nervous systems, all of which are largely mediated by the vagal nervous complex. HRV has also been found to be a measure of central neurobiological concepts such as executive functioning and cognitive load. The relatively simple and inexpensive acquisition of HRV data and its ease of network transmission and analysis make possible a promising digital epidemiology which can facilitate objective population health studies, as well as web based clinical applications. An intriguing example is the use of HRV data obtained at motor vehicle crash sites in decision support regarding life flight evacuations to improve triage to critical care facilities. This Research Topic critically addresses the issues of appropriate scientific and analytic methods to capture the concept of the Integrative Health and Well-being Model. The true nature of this approach can be appreciated only by using both traditional linear quantitative statistics and nonlinear systems dynamics metrics, which tend to be qualitative. The Research Topic also provides support for further development of new and robust methods for evaluating the safety and effectiveness of interventions and practices, going beyond the sometimes tepid and misleading “gold standard” randomized controlled clinical trial.

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