Institutional Approval of Research on Human Subjects

Guidelines for Human Experimentation

For various types of study involving human subjects and for various conditions, various organizations have produced guidelines for human subject research.

Prior to the Nuremberg Code, one of the earliest models for ethical human testing was formed in 1931. According to Sass (1983), the following are the key aspects of the 1931 Guidelines for Human Experimentation:

- Except in extraordinary extenuating circumstances, full, unequivocal, and complete consent from study participants is necessary.
- The potential benefits should outweigh the risks.
- Subjects under the age of 18 should be approached with caution.
- If microorganisms are present, extreme vigilance should be exercised.
- Subjects who are poor or weaker sections of the society should not be exploited.
- Animal testing should come first, and human experimentation should be avoided if there are still other ways to acquire data.

However, previous to their implementation, the vast majority of physicians discussing the restrictions were more concerned with the correct growth of medical knowledge than with the protection of vulnerable patients (Katz, 1997).

The Nuremberg Code was first published in 1949 as a set of principles for researchers working with human subjects. The 1931 Guidelines had been used as reference in creating the Nuremberg Code (Ghooi, 2011). The Nuremberg Code includes a requirement for informed consent, as well as other similarities to the Guidelines, such as both requiring risk to be balanced against potential benefits, and both discouraging the use of human experimentation when other methods of achieving the desired results are available. The Nuremberg Code also contains provisions not contained in the Guidelines, such as the need that subjects be offered the choice to exit the experiment at any moment, the study's purpose must be to benefit society, and precautions must be made to protect participants from even the remotest risk of injury.

The Declaration of Helsinki, published by the World Medical Association in 1964, is a code of scientific ethics. It was founded on the Nuremberg Code and focused on therapeutic medical research. Shamoo and Irving (1993) states that this document was one of the first steps in the process of establishing an institutional review board (IRB). Many IRBs use the Declaration of Helsinki codes to examine the ethical elements of clinical research (Mohamadi, Asghari, & Rashidian, 2014).

The Common Rule is the primary set of Federal regulations governing the protection of human subjects in research. It is found in Title 45, Code of Federal Regulations, Part 46 (45 CFR 46). Though some agencies have formed their own implementation of this code that supersedes portions or all of 45 CFR 46, it establishes the legislation, grounds for exemption, and the definition and formulation of institutional review boards (IRB).

An IRB (Institutional Review Board) is a properly constituted organization that has been formally established to review and oversee biomedical research involving human participants, according to FDA standards. An IRB has the power to approve, require adjustments in (to achieve approval), or cancel research in accordance with FDA standards. This group review plays an important role in the conservation of human research subjects' rights and welfare.

The goal of IRB review is to ensure that sufficient actions are taken to protect the health of persons participating as research subjects, both in advance and through periodic evaluation. IRBs employ a group method to examine study procedures and related materials (e.g., consent forms and investigator guides) to guarantee that human subjects of study's rights and welfare are protected.

Some agencies have established their own IRB implementation. The Institutional Review Board for the Protection of Human Subjects in Research's primary goal at University of New Hampshire is to “protect the rights and welfare of human research subjects by ensuring that physical, psychological, legal, and/or social risks to subjects are minimized” (UNH, 2022), justified by the importance of the research, and agreed to by subjects (informed consent). Second, the IRB aims to protect UNH and researchers from the potential negative repercussions of human subject research by aiding researchers in the design of their studies so that they conform with federal rules as well as UNH criteria.

The approval process guidelines at the United States Environmental Protection Agency go above and beyond what colleges, industry, and other government agencies accept and require. Human subjects research is frequently proposed by an investigator, reviewed by a supervisor, and then

reviewed by an Institutional Review Board in those organizations (IRB). EPA-funded or conducted research, on the other hand, is subject to greater scrutiny. For example, Human Subjects Officer (HSO) and Human Subjects Research Review Official (HSRRO) clearance is required for programs conducted or supported by the EPA. Controlled human exposure studies at the EPA's Office of Research and Development (ORD) are frequently subjected to up to 13 levels of internal and external review (EPA, 2022).

Pilot studies

A pilot study is a small-scale exploratory investigation of the feasibility of a project. Its purpose is to assist the researcher in fine-tuning data gathering processes and instruments, as well as preparing a better, more specific research plan. Because a pilot like this does not contribute to gaining insight, it is not deemed research and so does not require IRB approval. A pilot study's data cannot be used for research purposes. Regardless of the scale of the study, medical treatments or interactions for academic purposes, particularly those involving invasive procedures, require IRB approval.

<u>The necessity of gaining consent from research participants</u>

Consent is the moral and professional expression of a person's right to be treated with respect for their autonomy and self-determination. Informed consent gives participants with enough information about the study to allow them to make an informed, voluntary, and logical decision about whether or not to participate. The informed consent process has been viewed as vital both to safeguard individuals from harm and to protect the foundation of autonomy as a right in and of itself by permitting potential participants to make their own decisions (Ursin, 2009).

Because of historical changes, informed consent has become increasingly crucial, with a focus on the individual. Alternative consent procedures based on a broader societal concept of citizenship, education, and the development of trustworthy relationships will allow research to maximize its benefits while maintaining participant protection (Schofield, 2014).

Methods for data collection concerning human participants

Data collection is the process of acquiring and evaluating information on variables of interest in a systematic manner that allows researchers to answer research questions, test theories, and assess outcomes. All fields of study, including social and behavioral sciences, humanities, business, and others, use data collection as part of their research. While the methodologies differ depending on the discipline, the priority on accurate and honest data collection stays the same. We can get first-hand information and different perspectives into our research issue by collecting data. While methods and goals may vary per field, the overall data collection procedure is largely the same. Before we start collecting data, we must consider the following:

- The study's goal
- The type of information we will gather
- The procedures and methods we want to employ to acquire, store, and process the information

Bhandari (2021) states that we may need to gather quantitative or qualitative data, depending on the study questions:

- Quantitative data is represented by numbers and graphs, and statistical procedures are used to examine it.

- Words are used to express qualitative data, which is then examined using interpretations and categorizations.

We need to collect quantitative data if we want to test a theory, measure something thoroughly, or get large-scale statistical insights. On the other hand, we need to collect qualitative data if our goal is to explore concepts, analyze experiences, or obtain detailed insights into a specific setting. We can use a mixed methods strategy to collect both sorts of data if we have multiple goals.

Experimentation is essentially a quantitative approach to study. Qualitative approaches include interviews, focus groups, and ethnography. Surveys, observations, archival research, and secondary data collection can be both or either quantitative and qualitative methods.

Sample Selection

When we perform study on a group of people, we rarely have the opportunity to collect data from every single member of that group. Rather, we choose a sample. The sample is the number of people who will actually take part in the study and is influenced by administrative issues and costs.

We must carefully consider how we will select a sample that is typical of the entire group in order to make appropriate conclusions from our findings. In the methodology section of our paper or thesis, we should clearly explain how we chose our sample.

The population refers to the total group about which we wish to draw conclusions. The sample is the group of people from whom we will gather information.

Frame for sampling

The sampling frame is the list of people from which the sample will be selected. It should, in a fair scenario, include the complete target group excluding anyone who is not part of that group.

Size of the sample

The number of people we should include in our sample is determined by a number of factors, including the population's size and variability, as well as our study strategy. Depending on what we want to achieve with statistical analysis, there are several sample size calculators and algorithms (McCombes, 2022).

According to Kadam & Bhalerao (2010), the results of a study with a small number of subjects cannot be extended to the entire population since the sample size does not reflect the size of the target population. Furthermore, the study may not be able to distinguish between test groups, rendering it unethical. On the other side, if we investigate more participants than are required, we expose more people to the intervention, making the study unethical and wasting valuable resources, including the time of the researchers.

In general, the sample size for any study is determined by acceptable significance level, the study's effectiveness, size of the expected effect, the population's underlying event rate, the population's standard deviation (Kirby, Gebski, & Keech, 2002). The projected drop-out rate, an unequal allocation ratio, and the study's purpose and design are all elements to consider when calculating the ultimate sample size (Larsen et al., 1985).

Research Protocol and Instrumentation

A research protocol is a document that describes a clinical research project's background, rationale, objectives, design, technique, statistical considerations, and structure.

Protocol writing enables the researcher to analyze and critically assess published material on the research topic of interest, organize and review project processes, and serve as a guide during the investigation. The proposal is an essential document that allows the researcher to track the project's progress (Eaton & Santini, 2011). In order to conduct an acceptable study and receive trustworthy results, it is critical to understand the stages involved in designing a research protocol. Extra effort invested writing a good protocol will save failures later on while also assisting with analysis (Al-Jundi & Sakka, 2016).

Research instruments

The research instrument is commonly chosen by the researcher and is linked to the research approach. A study instrument is a tool that we can use to gather, measure, and evaluate data on our research topics. These techniques are most typically used to assess patients, clients, students, teachers, and staff in the health sciences, social sciences, and education. The efficiency of the research instrument has a big effects on the performance of the research. The more effective the research instrument, the farther genuine the findings. The most frequent instruments for gathering research data from research participants are questionnaires, Interviews, surveys, literature review, case study, focus group discussions, observations, and experiments.

Methods for outlining proper research procedure

Step 1: Select a topic – It is critical to complete this step correctly because it is the initial step in writing a paper. Within the parameters specified by the assignment and the instructor's directions, we should choose a topic. Once we've decided on a topic, it's a fine decision to frame it as a question.

Step 2: Search for information – Before we begin our research, we may need to conduct a search to see if there is enough information available to meet our goals and to establish the context of our study. Look up the keywords in the library's collection including encyclopedias and dictionaries as well as other sources including our book catalog, periodical databases, and Internet search engines. Lecture notes, textbooks, and reserve readings provide further background knowledge. We can also use the internet for searching the needed information.

Step 3: make notes and start writing – The next stage is to look at the resources we will be using for the paper and make a list of what we will need. Then, by collecting our thoughts and deciding on the format of the paper, we will compose a rough draft. After that, we must modify the draft as many times as we believe is required before submitting it to the instructor.

Step 4: cite sources properly – We will provide credit where credit is due using the author, publisher, title, date, URL from the notes. Citing serves two purposes: it offers correct acknowledgment to the writers of the materials utilized, and it allows individuals who read our work to imitate our study and access the sources we've given as references. The MLA and APA styles are two conventional citation styles. We want to avoid plagiarism by not using citations.

Step 5: proofreading – The final stage is to proofread the work we have done so far. We must examine the spelling, citations, grammar, and punctuation for any mistakes. We should make certain that the message we intend to convey to the reader has been clearly communicated.

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