Type: Research Paper

Subject: Ethics and Law

Subject area: Nursing

Education Level: Masters Program

Length: 4 pages

Referencing style: APA

Preferred English: US English

Spacing Option: Double

Title: ETHICAL REQUIREMENTS FOR RESEARCH

Instructions: ethical requirements for research readings: 1.burns and grove chapter 9 assignment: 1. write a 2-4-page paper that includes the following: a. explanation of the informed consent process for your research proposal. even if your proposal qualifies for expedited review, you still must address informed consent specifically for your proposal b. description of how you will protect participant privacy. hippa is insufficient for a research proposal. address protection of data and confidentiality. c. review of the irb process for your proposal. d. the risk benefit ratio for the participant in your proposed study. 2. the page requirement excludes the title and reference pages 3. utilize current apa format. a minimum of 2 scholarly references is required (excluding the textbook and bible) to support/justify your topic and provide enough background information to make your idea(s) clear to the reader.

Focus: research proposal-the study's main objective is to establish the effectiveness of the prone positioning method of treatment over the use of ventilators in easing breathing for the covid-19 patients.

Ethical Requirements for Research

Name

Institution

a. explanation of the informed consent process for your research proposal. even if your proposal qualifies for expedited review, you still must address informed consent specifically for your proposal

Informed consent can be viewed as the process through which the researcher informs all the potential research participants about all key elements of the study (Kadam, 2017). The informed consent is a crucial ethical element especially for research that deals with human subjects. The proposed research will undertake the informed consent process to ensure that participants are aware of all the major elements of the research before participating in the study. The participants will be required to read and sign a written consent document that contains the required information. If the participants sign the document, it will be deemed that they have given their consent to participate in the study. The informed consent document prepared for the proposed research will be based on the Federal regulations (45 CFR 46.116) and the revised 2018 Common Rule. The informed consent adopted for the proposed research will have five main elements.

First, the informed consent document will provide a statement that the project is a research and participation in the research is voluntary. The statement is aimed at reassuring the participants that they will not be forced or coaxed to participate in the research. Secondly, the informed consent document will provide a summary of the research. The document will highlight the purpose of the research, the duration which the research will take and the major list of procedures that the participants will be subjected to. Thirdly, the document will provide a list of reasonable, foreseeable risks and discomforts that the participants will be exposed to when taking part in the research. The document will show various strategies adopted to minimize the exposure to the risks. Fourthly, the informed consent document will show a detailed list of

benefits to the participants. Lastly, the informed consent document will demonstrate the alternative procedures or course of treatment. The main aim of the research is to establish the effectiveness of the prone positioning method of treatment over the use of ventilators in easing breathing for the covid-19 patients. Participants who will be exposed to prone positioning method will be provided information concerning the alternative procedure which is the use of ventilators in easing breathing.

b. description of how you will protect participant privacy. hippa is insufficient for a research proposal. address protection of data and confidentiality.

The participants will be assured that their privacy will be respected. The privacy condition will ensure that the personal data and information related to the participants will be respected. The researcher will therefore not reveal information and data related to the participants. Personal data and information that will be protected in the proposed research include names, birthdates, places of residence, and Covid-19 status among other details.

There are various strategies that will be adopted to ensure that the privacy and confidentiality of the participants will be ensured. First, the researcher will use participant codes to label data instead of using the actual names of the participants. The research will only refer the participants through their codes and ensure that the code-to-name match-ups will not be disclosed to any other person except the researchers.

Secondly, personal data and information related to the participants will be safeguarded with passwords and will only be accessible to the authorized researchers. Data will be held electronically but will not be uploaded to any website to reduce chances of hacking. The data will be stored in flash disks and external hard disks then placed in secure locations.

Thirdly, the data and information related to the participants will only be used for the purpose of the current research. The researchers will not be allowed to conduct any extra research beyond the proposed study using the collected data. Participants' data and information will be destroyed after the current study is complete.

c. Review of the IRB process for the proposal.

Federal regulations and the KP policy restrict the involvement of human subjects in research unless the research is reviewed and approved by the Institutional Review Board. The IRB is mandated to approve the research and research documents before the research is commenced. The IRB also reviews and monitors the progress of the research to ensure that the project complies with the set regulations. There are various documents that will be submitted to IRB for the proposed research. The documents include the CREC certification, the investigator training documents and the UH research credentials for non-UH personnel (Coleman, 2017).

The research will follow the IRB process flow to ensure that project is completed in accordance with the IRB regulations. First, the proposed study will be submitted to the IRB board through the electronic system. All the relevant documents and certifications will be filled correctly as required by submission guidelines. The second step will involve pre-reviewing by the IRB specialists. The submissions will be subjected to an assigned IRB specialist who will review and propose any clarifications needed. The third step will involve the formal review where the submissions will be submitted electronically to an IRB char or vice chair. The project will also be assigned to the next full board meeting. The fourth step is the post-review of the results where the board will classify the project into any of the five categories including approved, approved with administrative confirmation, approved with modifications, deferred and

disapproved. The last step is to complete the review where the researchers and the IRB team ensure continuous communication until the closure of the study is submitted.

d. the risk benefit ratio for the participant in your proposed study.

The risk benefit ratio evaluates various risks associated with the study and benefits attributable to the study. The risks can be categorized into physical, psychological and loss of confidentiality elements. Physical risks associated with the research may include physical discomfort, pain, injury and exposure to diseases. The current study will significantly reduce physical risks since the participants will only be subjected to evidence-based treatments. The exposure to physical risk is therefore moderate (a score of 3 in a range of between 1 and 5). Psychological risks which the participants in the current research may be exposed to include anxiety, depression and shock. However, the researchers will hold a counseling session with the participants hence drastically reduce the exposure to psychological risks. The last risk is loss of confidentiality where the data and information related to the patients might be accessed by unauthorized persons regardless of the strategies adopted to avoid such exposure. The study will adopt various strategies to prevent confidentiality issues hence drastically reduce the risk.

There are various benefits of participating in the research. First, the participants will take an active role in their own health care. Secondly, the participants will contribute towards the advancement of care against Covid-19 which is a major health issue. Thirdly, the participants will take an active role in society and assist in developing evidence-based practices. Fourthly, the participants will receive high quality and free health care services from experts during the entire research. Lastly, the participants will be part of a team that is striving to find a solution to the pandemic. There are three risks against five benefits hence the risk-benefit ratio is small.

References

Coleman, C. H. (2017). Reining in IRB Review in the Revised Common Rule. IRB, 39(6), 2-5.

Kadam, R. A. (2017). Informed consent process: A step further towards making it meaningful!. Perspectives in clinical research, 8(3), 107.