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SPECIFIC CONSIDERATIONS IN RESEARCH METHODS RELATED TO PEDIATRICS

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ABSTRACT

Respect for people, beneficence, and fairness are the three fundamental ethical concepts on which the ethics and regulations of clinical research are based. In order to interpret the requirements of these three principles in the particular situation of research involving human beings, ethical codes and regulations contain rules or norms. Children are viewed as vulnerable subjects since they are unable to give informed consent due to a lack of capacity or competence. In light of this, it is generally forbidden for minors to participate in research without their parents' or guardians' consent, according to the regulations. Additionally, consent from children who are old enough to make informed decisions is necessary. When procedures or interventions entail a larger than minimal risk but little likelihood of immediate benefit, special explanations must be made before include children in research initiatives. It highlights the continuing nature of ethical considerations, emphasising how crucial it is to take them into account not only before but even after doing research. In terms of the children's best interests, the study examines some of the major ethical problems that develop during and after research involving children.

KEYWORDS: Research, Ethics, Children.

Methods: Material related to Research Methods related to Pediatrics is collected by online articles, journals, guidelines and websites.

INTRODUCTION

RESEARCH: The word "research" originated from the old French word "recerchier" meaning to search and search again.[1] Research is defined as the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies and understandings.[2]

ETHICS

Learning what is right or wrong and then acting accordingly are both aspects of ethics; nonetheless, doing "the right thing" is far from simple. The majority of moral conundrums in this region don't just come down to yes or no.[3]

Ethical values, such as respect, honesty, justice, responsibility, etc., are examples of values that serve as a guide for how we should conduct. Principles of ethics or morality are usually used to describe statements about how these values should be applied.

Children are the beneficiaries of rights outlined in a number of international human rights instruments. Each nation has its own set of moral laws (ethical rules) and numerous international organizations and academics have argued that these laws play a crucially important role in creating moral guidelines for studies involving children.

Following concepts have served as the foundation for the ethical guidelines in child research:

1. **THE LESS VULNERABLE ARE FIRST:** Before conducting any research which include children as its subject the research must be reviewed and approved by Institutional Review Board " The IRB is required to determine… where appropriate, that studies has been conducted first on animals and adult humans, then on older children, prior to involving infants." (Recommendation 2B)[4]

This recommendation represents how the principle of justice's mandate that vulnerable people be given special protection from the burden of research is understood. Older children are seen as less susceptible than adults, who are then seen as less vulnerable than newborns. Researchers must convince the IRB that conducting study on children is vital before conducting such research on adults or animals.

2. **INFORMED CONSENT/ ASSENT:** The fundamental paradigm for defending patients' legal rights and directing the moral practice of medicine is now informed consent. It can be applied in a variety of settings, including those that are legal, ethical, or administrative.

The Nuremberg Code 1949 appears to introduce the concept of consent for the participation of children in research.[5]

- Assent is an active declaration of a desire to participate in research by a person who is too young to give legal consent but mature enough to understand the study, as opposed to consent, which is a binding agreement between the researcher and a potential study subject or their authorized representative.
- Regardless of the legal age of consent, it is critical to provide information to minors that is appropriate for their comprehension level through the appropriate choice of language, format, and volume of information, as well as confirming that they understand the contents. It is crucial to take into account differences in their decision-making capacity based on their level of development, social, environmental, and family-related factors, as well as their medical history.[6]

According to the present guidelines released by ICMR under the title "National Ethics Guidelines for Bio- Medical Research involving Children" Oral assent must be gained from children between the ages of 7 (84 months and older) and 12 in the presence of the parent or other legally acceptable person. Written consent must be sought for kids aged 13 to 18 years old. Written consent must be sought whenever a child turns 13 while the study is ongoing. To confirm that the child's verbal assent has been taken in situations involving verbal assent, the parent's countersignature must be sought.[7] It all should be done only after receiving adequate information regarding the study's procedures, potential risks and benefits, and expected outcomes.

This is essential to safeguard children's rights, including protection from potential damage, invasion of privacy, legal dangers, and psychological or emotional stress, when they participate in research.

Mature Minors

When necessary, IRBs may waive the need for parental or guardian consent. "It is not a reasonable requirement… provided an appropriate mechanism for protecting the children is substituted" (Section 46.408). The regulations provide a study as an illustration of how obtaining parental consent could not be reasonable in some situations on "neglected or abused children"[8]

Documentation of Assent

The purpose of informed consent, parental permission and assent are entirely different from those of their documentation on a consent form". Because the primary purpose of documentation is to protect the interests of the investigator and the institution against those of the subject, it seems generally unnecessary to document assent except in those cases in which the IRB determines that parental or guardian permission is unnecessary. When young children are invited to sign forms, the principal purpose is to enhance their sense of participation in the process.

3. **PROCEDURES:** The researcher must avoid any research techniques that could be physically or psychologically harmful to the youngster. Additionally, the researcher has a duty to always employ the least strenuous study method. The definition of psychological injury and methods for minimizing or eliminating it may be challenging in some circumstances, but the investigator is still responsible for doing so. The researcher is required to identify alternative ways of gathering the data or to stop the study when harm appears to be unavoidable. Besides, extra time and support should be given for the children. Similarly, dissemination of findings will need to be informed by an understanding of the specific communication needs of the children and their families.[9]

Requirements Varying depending on the Degree and Kind of Risk

MINIMAL RISK

As defined in DHHS regulations (Section 46.102g), " Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinary encountered in daily life or during the performance of routine physical or psychological examinations or tests."

The National Commission provided examples of procedures presenting no more than minimal risk: Routine immunizations, Modest change in diet or schedule, physical examinations, obtaining blood and urine specimens and development assessments, Routine tools of behavioral research, such as most questionnaires, observational techniques, noninvasive physiologic monitoring and puzzles may be considered to present no more than minimal risk.

MORE THAN MINOR INCREMENTS ABOVE MINIMAL RISK

Approval of such procedure may be granted only by the DHHS Secretary after consultation with a panel of experts in pertinent disciplines.[10]

4. **Anonymity and Confidentiality:** means that at no time will the researcher or anyone associated with the project know the identity of the participants. In anonymous research, the information collected does not contain any identifiable information, and the risk of being able to attribute data to particular individuals is low while confidentiality research means that proper safeguards are in place to protect the privacy of participants and their information from unauthorized access, use, disclosure, modification, loss, and theft.[11] When a possibility exists that others may gain access to such information, this possibility, together with the plans for protecting confidentiality, should be explained to the participants as part of the procedure of obtaining informed consent. The purpose of this guideline is to provide researchers with information on anonymity and confidentiality with respect to research involving human participants.

5. **Peril:** In the course of child-focused research, if the researchers learn of facts that could peril the child's safety. The research must be discontinued until the problem has been resolved if there is ever a sign that a child's safety or well-being is being compromised throughout the research process. Its the responsibility of researcher to notify parent or legal guardian if the kid looks to be badly impacted by the research, and the child and family must be provided with the necessary support.

6. **Outcome:** When the outcomes from research procedures are unpleasant and were previously unanticipated, the researcher should promptly take the necessary steps to address these outcomes and should modify the techniques if they are to be used in future studies.

7. **Reporting A Finding:** When reporting findings, offering opinions, or offering recommendations, care should be taken because the investigator's comments may have an unintended impact on parents and children. Giving advice is acceptable in some types of research if it is a necessary component of the study, has been approved by the participant, and has undergone an ethics review. However, in other cases, a researcher can find evidence pointing to the existence of psychological or physical issues that a subject might seem to be ignorant of. If the investigator considers that failing to do so may harm the

participant's future wellness, it is their duty to bring up the subject with the participant. If the problem is serious and the investigator is unable to help, a reliable source of expert counsel should be suggested.

8. **Implications of findings:** Investigators should be mindful of the social, political and human implications of their research and should be especially careful in the presentation of findings from the research. This principle, however, in no way denies investigators the right to pursue any area of research or the right to observe proper standards of scientific reporting.[12]

DISCUSSION

Several ethical standards see research on minors as a moral obligation. Although there are of course numerous nuances and variations, and the situational aspects of how concepts are understood, interpreted, and used can differ from place to place, these principles are universal. The conduct of research ethical issues are closely related to the content of social or therapeutic theories in studies involving children. To improve overall research conditions and avoid favouring any one party in particular, a number of criteria must be taken into account.

CONCLUSION

It is crucial to encourage more careful attention to the complex ethical issues that arise when doing research involving children in order to protect and promote the rights, dignity, and well-being of children in and via research. Before doing research on children, it must be proven beyond a reasonable doubt that no equivalent findings could come from subjects who are able to give informed consent. Even if this is shown, children's susceptibility must always be taken into account, and they shouldn't participate in research unless there is a chance they will gain something from the study's findings. Children should be told by researchers that they respect their freedom to leave the study at any time. it is the responsibility of researchers to safeguard the rights and welfare of research participants. Therefore, while research activity must be regulated and the researchers must ensure that the subjects' rights to informed consent, confidentiality, and unrestricted communication are always protected, children should be given the opportunity to express their opinions and learn about themselves and their rights.

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