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ETHICAL CONSIDERATIONS IN NURSING RESEARCH

A good research problem conforms to moral, ethical and legal standards of scientific inquiry. a good research should have deep concern for human welfare and sensitivity for the rights of research subjects. Any research that may be harmful, violates the ethical code of nursing may be illegal.

GOVERNMENT REGULATIONS FOR PROTECTING STUDY PARTICIPANTS:

The Nazi trails at Nuremberg brought to light many cruel scientific experiments done on human beings without their consent. Government throughout the world fund research and establish rules for adhering to ethical principles.

World Medical Assembly: The world Medical Assembly adopted HELSINKI DECLARATION ON BIOMEDICAL RESEARCH (June 1964) was drawn to safe guard human subjects against cruelty in the name of science. All medical and nursing researchers are expected to abide by the Helsinki declaration when dealing with human subjects. The declaration was subsequently amended several times ,most recently in Edinburgh in October 2000.

Canada: Health Canada specified the Tri council policy statement: ethical conduct for research involving humans as the guidelines to protect study participants in all types of research.

Australia: The national health and medical research council issued the National statement on Ethical conduct in research involving humans in 2007 and also issued a special statement about incentive payments to study participants in 2009.

United States: The national commission for protection of human rights established the national research act, issued the Belmont Report, which provided as a model for many disciplinary guidelines. The U.S. Department of Health and Human services has issued ethical regulations for human research. These regulations have been revised in 2005.

American Nurses Association: The American Nurses Association issued ethical guidelines in the conduct,Dissemination, and Implementation of Nursing research (1995) ,revised in 2001, The Code of Ethics for Nurses with Interpretive statements that covers ethical issues for Nurses and Nurse Researchers.

ETHICAL DILEMMAS IN CONDUCTING RESEARCH:

1. Research that violates ethical principles are rarely done .There is situations in which the participants' rights and study demands are in direct conflict, posing ethical dilemmas for researchers.

2. Nurse researchers are confronted with conflict of interest situations, in which the expected behavior of Nurse Researchers conflicts with the expected behavior as nurses

ETHICAL PRINCIPLES FOR PROTECTING STUDY PARTICIPANTS:

The Belmont report articulated three main principles on which standards of ethical conduct in research are based:

1. Beneficence

2. Respect for human dignity

3. Justice

1. Beneficence:

Beneficence imposes a duty on researchers to minimize harm and maximize benefits. It includes:

i.The right to freedom from harm and discomfort: Researchers have an obligation to avoid, prevent or minimize harm (nonmaleficence) in studies with humans. Participants must not be subjected to unnecessary risk of harm or discomfort. Ethical researchers must use strategies to minimize all types of harm and discomforts.

ii. The right to protection from exploitation: Participants need to be assured that their participation or information they might provide will not be used against them.

2. Respect for humanity: this is the second principle and it includes:

i. The right to self-determination: It means that the participants can voluntarily take part in a study, without risk of prejudicial treatment. It also means that people have the right to ask questions, to refuse to give information, and to with draw from the study.

ii. The right to full disclosure: Full disclosure means that the researcher has fully described the nature of the study, the person's right to refuse participation, the researcher's responsibilities and the likely risks and benefits.

3. Justice: The third principle is the right for justice. It includes:

i. The right to fair treatment: It is the equitable distribution of benefits and burdens of research. Participant selection should be based on study requirement and not on group's vulnerability. Distributive justice also imposes duties to neither neglect nor discriminate gainst individuals or groups who may benefit from research.

ii. The right to privacy: Researchers should keep in mind that research is not more intrusive than it needs to be and that participant's privacy is maintained continuously. Participants have the right to expect that their data will be kept in strict confidence.

ICMR POLICY STATEMENT ON ETHICAL CONSIDERATIONS

Indian council of medical Indian research (1980) formulated a policy statement on ethical consideration involved in research on human subjects. It includes the following:

1. **Institutional Ethical committee:** According to ICMR all medical colleges and research centers involved in clinical research would form ethical committees. The ethical committee should consists of :
    i.Experienced clinicians
    ii.phamacologist
    iii.one or two non-medical persons as guides
    iv.A lawer
    v. A member from outside the institute

The committee should meet at least once in three months and review all proposals for clinical research proposed by the investigator in the institute. The committee must approve all the researches undertaken by the members in the institution.

2. **Support of clinical research by the council:** The council would not consider support for any proposal for research on human subjects unless the research proposal has been approved by the ethical committee of the institute concerned. The council would take on the responsibility of assessing proposals on ethical considerations for an interim period of one year. The council would also evaluate the entire proposal that might be sent for international publications.
3. **Implementation of Ethical committee guidelines:** The ethical committee should monitor the implementation of these guidelines and check whether the principles laid down regarding research on human beings are followed and recommendation made by the IEC is observed.

4. **Drug Trials:** The council would make it clear that clinical evaluation of any new drug to be used for prophylactic, diagnostic or therapeutic purposes should be carried out only after the approval, as is necessary under law and IEC.
5. **Clinical Trials with plants and indigenous system of Medicine:** The council would suggest that clinical evaluation of plants utilized for therapeutic purpose be approved by the IEC.
6. **Informed consent:** The council would verify whether all the principle laid for obtaining informed consent is strictly adhered by the investigator
7. **Clinical research on children;** should be carried out only if possibility of some direct benefit to the child taking part in the trial. Voluntary informed consent would carried from the parent or guardian concerned.
8. **Clinical research on Mentally Deficient patients:** It should be carried out only if the treatment would cure the client or it would add more information to the disease or treatment. Here again informed consent should be obtained from the parent or guardian.
9. **Clinical research on prisoners, students or Laboratory personnel:** Research on prisoners should never be carried out as it is difficult to obtain informed consent and inducements offered to them for taking part would make it unethical. Similarly on students and laboratory personnel on rare occasions the research would be perfectly ethical. Here the researcher should be in a position to influence the subjects to take part in the study.
10. **Financial reimbursements to participants:** The IEC would judge about reimbursement in particular situations depending on the time required by the subjects to participate in the study, procedure needed to be performed on the subjects and local factors such as cost, transportation etc..
11. **Publication of paper in Indian journal of Medical Research:** The research papers that have been based on clinical research carried out only after the approval of the IEC would be considered for publication in Indian Journal of Medical Research.

Clinical research supported by agencies other than ICMR: The guideline laid down by the ICMR is designed to assist all investigators in the country who are involved in carrying out the research on human subjects. The other agencies involved supporting research in India would incorporate these guidelines and the ICMR would time to time organise meetings of all the agencies supporting research to make uniform the ethical safe guards.