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1. ETHICS IN NURSING RESEARCH www.drjayeshpatidar.blogspot.com 2. DEFINITION Ethics in nursing research can be defined as the act of moral principles which the researcher has to follow while conducting nursing research to ensure the rights & welfare of individuals, groups or community under study. www.drjayeshpatidar.blogspot.com 3. IMPORTANCE OF ETHICS IN NURSING RESEARCH Protect the vulnerable group & other study participants from harmful effects of the experimental interventions. Participants are safeguarded from exploitation researchers. Establish risk – benefit ratio for the study subjects Ensure the fullest respect, dignity, privacy, disclose of information & fair treatment for study subjects. Build the capability of subjects to accept or reject participation in study & to have access to informed or written consent for participation in research www.drjayeshpatidar.blogspot.com 4. ETHICAL PRINCIPLE IN NURSING RESEARCH 1. Principle of beneficence 2. Principle of respect of human dignity 3. Principle of justice www.drjayeshpatidar.blogspot.com 5. 1. Principle of beneficence Establishing the positive risk benefit ratio, where the risk of the research should never exceed expected benefits for people from knowledge generated by the research activity. A potential risk of the research study must be carefully assessed & participants are protected from any harmful effect of research activity. www.drjayeshpatidar.blogspot.com 6. Count… In addition to physical harm, study subjects are also protected from expected adverse psychological consequences caused by research study. For example, psychological or emotional distress caused from self- discloser, introspection, fear of the unknown, or interacting with a stranger. www.drjayeshpatidar.blogspot.com 7. Count… Research must be conducted by a scientifically qualified expert to avoid undue discomfort or distress to study participants. Participants must be provided with maximum physical, psychological, social & religious comfort & undue disturbance & time utilization of the subjects should be avoided. www.drjayeshpatidar.blogspot.com 8. 2. Principle of respect of human dignity This principle of the ethics emphasizes on the freedom of choice, where participants have right to accept or reject to be a part of the research study. Participants have full right to question the researcher for any additional information or clarification of doubts. Participants have right to quit from the study at any stage of the research study.www.drjayeshpatidar.blogspot.com 9. Count… A fully informed consent must be taken from the participants. In case of the fetus, child, psychological, neurological or physical inability to give informed consent; this can be obtained from parents or legal guardians. The contents of an informed consent must include the following: Purpose of the research study. Procedural process & any intervention involved in the study. Expected time & nature of participant's involvement in the www.drjayeshpatidar.blogspot.com 10. Count… Type of data/information to be obtained for respondents. Details of the potential discomfort or risk for participants in the study. Details of the support available in case any harm occurs to participants. Mechanism to protect privacy & anonymity of participants. Contact detail to collect information & clarification about doubt. Statement about voluntary participation of subjects & right to termination without any penalty. Describe of the expected benefits of the research study. www.drjayeshpatidar.blogspot.com 11. 3. Principle of justice This ethical principle directs the researchers to abide by the participant's right of fair treatment & maintenance of privacy. The fair & nondiscriminatory selection of the participants such as any risk & benefits will be equally shared by study participants. Participant's selection should be based on research requirement & not convenience, gullibility or compromised position of certain types of people. www.drjayeshpatidar.blogspot.com 12. Count… The nonprejudicial treatment of individual who decline to participate or who withdraw from the study after agreeing to participate. Anonymity of participants & confidentiality of information must be maintained. No information collected from study participants can be used for other than research purpose. The vulnerable subjects such as children, pregnant women, mentally ill patients, physically disabled, terminally ill & institutionalized (prisoners) people, who are conveniently & easily accessible must be protected from overuse & undue use for research purpose.www.drjayeshpatidar.blogspot.com 13. www.drjayeshpatidar.blogspot.com 14. INTRODUCTION Indian Nursing Council (INC) has published the code of Ethics for Nurses in India in year 2006. The code of ethics for nurses in critical for building professionalism & accountability. Ethical consideration are vital in any area dealing with human beings including nursing research because they represent values, rights & relationships. The code of Ethics for nurses in India (2006) are as follows: www.drjayeshpatidar.blogspot.com 15. 1. The nurse respects the uniqueness of an individual in provision of care Nurse Provides care for individuals without consideration of caste, creed, religion, culture, ethnicity, gender, soci oeconomic & political status, personal attributes or any other grounds. Individualizes the care considering the beliefs, values & cultural sensitivities. Develops & promotes trustful relationship with individual's Recognizes uniqueness of response of individuals to interventions & adapts accordingly. www.drjayeshpatidar.blogspot.com 16. 2. The nurse respects the rights of individuals as partners in care & helps in making informed choices Nurse Appropriate individual's rights to make decisions about their care & therefore gives adequate & accurate information for enabling them to make informed choices. Respects the decisions made by individual (s) regarding their care Protect public from misinformation & misinterpretation. Advocates special provisions to protect vulnerable individual/groups. www.drjayeshpatidar.blogspot.com 17. 3. The nurse respects individuals' rights to privacy, maintains confidentiality & shares information judiciously Nurse Respects the individual's rights to privacy of their personal information Maintains confidentiality of privileged information except in life threatening situations & uses discretion in sharing information. Takes informed consent & maintains anonymity when information is required for quality assurance/academic/legal reasons. Limits the access to all personal records written & computerized to authorized persons only. www.drjayeshpatidar.blogspot.com 18. 4.The nurse maintains competence in order to render quality nursing care Nurse Nursing care must be provided only by a registered nurse. Nurse strives to maintain quality nursing care & upholds the standards of care. Nurse values continuing education, initiates & utilizes all opportunities for self development. Nurse values research as a means of development of nursing profession & participates in nursing research adhering to ethical principles. www.drjayeshpatidar.blogspot.com 19. 5. The nurse is obliged to practice within the framework of ethical, professional & legal boundaries Nurse Adheres to code of ethics & code of professional conduct for nurses in India developed by India Nursing Council. Familiarizes with relevant laws & practices in accordance with the law of the state www.drjayeshpatidar.blogspot.com 20. 6. The nurse is obliged to work harmoniously with members of the health team Nurse Appreciates the team's efforts in rendering care. Cooperates, coordinates & collaborates with members of the health team to meet the needs of people. www.drjayeshpatidar.blogspot.com 21. 7. The nurse commits to reciprocate the trust invested in nursing profession by the society Nurse Demonstrates personal etiquettes in all dealings. Demonstrates professional attributes in all dealings. www.drjayeshpatidar.blogspot.com 22. www.drjayeshpatidar.blogspot.com 2. Objectives Objectives At the completion of this unit the students will be able to: Identify the historical context for the development of ethical codes Define three ethical principles necessary for conducting research Discuss human rights that require protection in research Describe the informed consent process Define the function of Institutional Review Boards Examine the risk-benefit ration of studies conducted in clinical agencies Critique the ethical information provided in a published study 3. Ethical vs. Unethical Research Ethical vs. Unethical Research Ethical studies protect subjects and are carried out using scientific principles. Unethical research includes: Scientific misconduct Fraud, research protocol violations Fabrication, falsification, forging of data Plagiarism Putting subjects at risk without consent 4. Elements of Ethical Research Elements of Ethical Research Protecting human rights Understanding informed consent Understanding institutional review of research Balancing benefits and risks in a study 5. Unethical Studies Unethical Studies Since the 1940s, four experimental projects have been highly publicized for their unethical treatment of human subject: Nazi medical experiments Tuskegee syphilis study Willowbrook study Jewish chronic disease hospital study 7. Ethical Codes and Regulations Ethical Codes and Regulations Nuremberg Code (1949) Declaration of Helsinki (1964) Department of Health, Education and Welfare (DHEW) regulations (1973) National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978) 8. Nuremberg Code (1949) Nuremberg Code (1949) 1. The voluntary consent of the human subject is absolutely essential… 2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature. 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment. 9. Continue… Continue… 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury. 5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur, except, perhaps, in those experiments where the experimental physicians also serve as subjects. 6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment. 7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death. 10. Continue… Continue… 8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment. 9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible. 11. Continue… Continue… 10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject... (Levine 1986, pp. 425-426) 12. Declaration of Helsinki Declaration of Helsinki Therapeutic research Results might benefit participants Nontherapeutic research Results are not of benefit to participants, but might be in the future 13. National Commission for the Protection of National Commission for the Protection of Human Subjects Human Subjects Ethical principles: Principle of respect for persons Principles of beneficence Principle of justice These may be seen in the DHHS Belmont Report (1978). 14. Principle of Respect for Persons Principle of Respect for Persons Self-determination (participation and withdrawing) No coercion Full disclosure, no deception Voluntary consent Persons with diminished autonomy have special protections 15. Principle of Beneficence Principle of Beneficence Freedom from harm Freedom from exploitation Risk/benefit ratios High anticipated benefit may balance high risks 17. Title 45 Part 46 Protection of Human Title 45 Part 46 Protection of Human Subjects Regulations Subjects Regulations 1. Protection of human subjects in research – Additional protection for pregnant women, human fetuses, neonates, children, and prisoners 2. Documentation of informed consent 3. Implementation of the IRB process (DHHS, 2005) 18. Additional Government Protections Additional Government Protections US Food and Drug Administration (FDA)—regarding clinical investigations with human subjects involving products Animal studies also included Clinical trials for drug investigations must comply with FDA regulations. 19. Health Insurance Portability and Health Insurance Portability and Accountability Act (HIPAA) Accountability Act (HIPAA) Also known as: Public Law 104-191 Implemented in 2003 to protect individuals' private health information HIPAA privacy rules are very strict. Affects research studies by requiring patient consent so as to use private health information 20. Human Rights Human Rights Right to self-determination Right to privacy Right to anonymity and confidentiality Right to fair treatment Right to protection from discomfort and harm 21. Self-Determination Self-Determination Humans are autonomous agents with freedom to conduct their lives as they choose. This principle would be violated by: Coercion: forcing someone to be in study Covert data collection: subjects are unaware study is taking place Deception: misinforming subjects about the study 22. People with Diminished Autonomy People with Diminished Autonomy Are given extra protection of right to self-determination because of decreased ability or inability to give informed consent. These people include: Legally and mentally incompetent subjects Neonates and children Terminally ill subjects People confined to an institution Pregnant women and fetuses 23. Right to Privacy Right to Privacy The freedom that an individual has to determine the time, extent, and general circumstances under which private information will be shared with or withheld from others 24. HIPAA Privacy Rule HIPAA Privacy Rule Protects individually identifiable health information De-identifying protected health information is allowed only if the following are removed: Name, geographic information, all dates, phone (+fax/e-mail), SS, medical record numbers, certificate numbers, vehicle identifiers, device identifiers, URLs, IP address, fingerprints/voiceprints, full-face photos, all identifying numbers 25. Continue… Continue… Data use agreement—must be included in the consent Covered entities Health care providers Health care plans Employers Health care clearinghouses 26. Right to Anonymity and Confidentiality Right to Anonymity and Confidentiality Confidentiality: researcher refrains from sharing information with others Breach of confidentiality: unauthorized access to raw data Anonymity: no one, not even the researcher, knows the identity of the subjects 27. Right to Fair Treatment Right to Fair Treatment Based on the principle of justice Selection of subjects and their treatment during the study are fair for all Prevents coercion of subjects (i.e., paying subjects large sums of money to participate) 28. Right to Protection from Discomfort and Right to Protection from Discomfort and Harm Harm No anticipated effects Temporary discomfort Unusual levels of temporary discomfort Risk of permanent damage Certainty of permanent damage 30. Essential Information for Consent Essential Information for Consent 1. Introduction of research activities 2. Statement of research purpose 3. Selection of research subjects 4. Explanation of procedures 5. Description of risks and discomforts 6. Description of benefits 7. Disclosure of alternatives 8. Assurance of anonymity and confidentiality 9. Offer to answer questions 10. Voluntary participation 11. Option to withdraw 12. Consent to incomplete disclosure 31. Institutional Review Board (IRB) Institutional Review Board (IRB) 1974 National Research Act requires research study review Who serves on the board? Functions Protection of rights and welfare Voluntary informed consent Benefits exceed risks 32. Institutional Review of Research Institutional Review of Research Exempt from review procedures: no risk Expedited review procedures: minimal risk Complete institutional review procedures Reviewing studies using vulnerable populations Have greater than minimal risk 33. Categories in Exempt Research Categories in Exempt Research Research on regular educational strategies Data are recorded so subjects cannot be identified Only public officials can be identified. Existing data can be collected if no subject identifiers are present. Studies about public benefit programs Taste and food quality evaluation 34. Categories in Expedited Research Categories in Expedited Research Collection of hair, nails, teeth, dental plaque Collection of excreta and external secretions Recordings using noninvasive procedures and study of existing data Collection of blood samples from subjects in good health Moderate exercise by healthy volunteers Research on behavior without stress Research on drugs that are exempt from new drug investigation 35. Influence of HIPAA Privacy Rule on Influence of HIPAA Privacy Rule on Institutional Review Boards Institutional Review Boards HIPAA must be followed. Read report carefully. Think about procedures that were implemented. Consider how data were collected. Were the patients put at undue risk? What is the risk/benefit ratio? 36. Critiquing the Ethics of a Study Critiquing the Ethics of a Study Was study approved by the appropriate IRB? Was informed consent obtained from subjects? If subject is incompetent, did legally authorized representative give consent? Were rights protected during sampling and data collection and analyses? Was privacy protected during study and in final report? Was benefit/risk ratio of the study acceptable? 1 Introduction to Nursing EthicsCatherine Hrycyk, MScN, RN 2 Ethical vs. Legal Ethical Ought to Prudent Knowledge Legal Must 3 Ethical Principles Autonomy Beneficence Nonmaleficence JusticeVeracity Fidelity 4 Autonomy Definition: "autos" = self, "nomos" = ruleRight to self determination Treat each individual as an autonomous subject Individuals have right to make treatment decisions Must have a capacity to make decisions independently: Developmental considerations Health related challenge 5 Paternalism / ParentalismRestricting autonomy One individual assumes the right to make decisions for another Considered acceptable when patient does not have decision making capacity 6 Beneficence & NonmaleficenceDo good Act in a way that benefits patients Centerpiece of caring Closely related to nonmaleficence What is 'good'? Do NOT cause harm PREVENT harm REMOVE harm More binding than beneficence Because you're going beyond just trying to do good to that pt, you're trying to prevent harm 7 Justice Treat alike cases alikeDistributive justice refers to distribution of benefits and burdens Equally disbursed according to Need Effort Societal contribution Merit Legal entitlement 8 Fidelity Duty to be faithful to commitmentsMake a promise, follow through: Includes implicit and explicit promises Implicit – promises that are implied, not verbally communicated Explicit – promises that are explicitly communicated 9 Veracity The obligation to tell the truth and not to lie or deceive others Often a source of ethical challenges arising from differences in personal beliefs and unique cultural features 10 Respect for Persons Closely tied to autonomyPromotes ability of individuals to make autonomous choices and should be treated accordingly Autonomy is preserved through advanced directives 11 Double Effect Some actions can be morally justified even though consequences may be a mixture of good and evil Must meet 4 criteria: The action itself is morally good or neutral The agent intends the good effect and not the evil (the evil may be foreseen but not intended) The good is not achieved by the evil There is favorable balance of good over evil 12 Ethical Frameworks Utilitarianism: Duty based (Deontology):Moral rightness of an action is determined by the consequence. Distributive justice: Greatest benefits for the greatest number of people. Duty based (Deontology): Duty to do or to refrain from doing something. Decisions are made because there is duty! 13 Ethical Frameworks Virtue ethics: Principalism:Actions consistent with certain ideal virtues. Decisions should be directed at maintaining virtues (honesty, courage, compassion, etc.). A person using this approach may ask themselves, "If I carry out these actions, what kind of person will I be?" Principalism: Use of ethical principles instead of theories to evaluate actions. More likely to be used by nurses in practice: Requires knowledge of principles, rather than knowledge of theories 14 Ethical Issues Moral distress: Moral/ethical dilemma:Two or more clear principles apply but they support inconsistent courses of action Moral uncertainty/conflict: When the nurse is unsure which moral principle to apply, or even what the problem is. Common with new nurses. Moral distress: When the nurse knows the right thing to do but organizational constraints keep them from doing it Moral outrage: An individual witnesses an immoral act by another but feels powerless to stop it. 15 Ethics in Professional PracticeANA Code of Ethics: Applies to all nurses in all healthcare settings Ethical principles agreed upon by members of the nursing profession Sets standards of conduct and behaviors for nurses ANA Ethics Website Key Points: Primary commitment is to patient (individual, family or community). Demonstrates compassion and respect for all patients regardless of patient status. Promotes the health and welfare of patients. Accountable for individual practice. Maintains and increases own knowledge base. Works to improve healthcare environment for providers and patients. 16 Ethics in Professional PracticeInternational Council of Nurses (ICN) Code of Ethics: 4 fundamental responsibilities of Nurses Promote health Prevent illness Restore health Alleviate suffering ICN Code of Ethics Website 17 Nurses Rights in Ethical SituationsNurse has the right to refuse to participate in giving care to a client if they disagree with care on ethical grounds. Upheld by ANA Assure client is not abandoned for care The Joint Commission (TJC) requires employers to establish policies and mechanisms to address staff requests not to participate in aspects of care that conflict with cultural values or religious beliefs. 18 NCSBN Professional BoundariesBoundaries: Space between nurse's power and client's vulnerability Crossings: Brief excursions across boundaries that may be inadvertent, thoughtless, or even purposeful if done to meet a specific therapeutic need Violations: results when there is confusion between the needs of the nurse and those of the client. Sexual misconduct: extreme form of violation that is seductive, sexually demeaning, harassing or interpreted as sexual by the client. 19 Boundary Crossings Examples (1)Excessive self-disclosure - the nurse discusses personal feelings or aspects of their personal life in front of the pt Secretive behavior - the nurse keeps secrets with the client or becomes guarded when someone questions their interactions "Super nurse" - the nurse believes only he or she can meet the needs of the client Selective communication - the nurse fails to explain actions or actions of care 20 Boundary Crossings Examples (2)Singled out client treatment/client attention to the nurse – the nurse spends inappropriate amounts of time with the client, client may give gifts to the nurse Flirtations - never appropriate! You and me against the world behavior - nurse views client in a protective manner Failure to protect the client - nurse doesn't recognize sexual feelings towards the client 21 Nurse's Challenge Be aware of your own and your patients' feelings and beliefs. Be cognizant of your own and patients' culturally negotiated behaviours. Be observant of the behavior of other professionals. Always act in the best interest of the client! 22 Processing Ethical DilemmasClarify / determine whether or not a dilemma exists Gather all relevant information Identify options Make a decision Caution: reflect on your values! Act Evaluate 23 Withholding / Withdrawing CareCan withhold "inhumane" treatment if it is "virtually futile" in extending life – usually DNR Allowing to die vs. making die: What is the difference? 24 Euthanasia Intentional termination of life: Terminal sedation:Active – purposefully causing the persons death: Generally illegal May be legal under certain circumstances Passive – hastening of death by altering some form of support Terminal sedation: Doctrine of 'double effect '(the intent of the act) Do a thing with one intent, but causes something else to happen – morphine OD Procedure used in dying pt's to relieve suffering. Pt's who are in extreme pain may chose terminal sedation 25 Assisted Suicide Patient actively seeks physician/nurse to 'help" them commit suicide. Criminal offense in majority of states: May be legal in certain circumstances in Oregon, Washington, and Montana. Under review in California. Usually pa. is given prescriptions in amounts that are legal and they decide if they want to use it. 26 Defining Death (FYI) Uniform Determination of Death ActPatient is dead if any one of the following conditions are met: Cardiopulmonary death Neurological death Evidenced by flat EEG Not PVS – (persistent vegetative state) 27 Conclusion Know yourself and your valuesProtect your patient by intervening if you identify an ethical question Know facility policy for access to the ethics committee Know your responsibilities with regard to informed consent Respect the patient's advance directives Chapter 10Ethical Issues in Nursing ResearchPerspectives for Assessing Ethical Acceptability • Utilitarian Perspective - the good of a project is defined by the consequences of the results • the greatest good for the greatest number • the end justifies the means • each researcher may have a different idea about what is "good" Deontological Perspective • Proposes absolute moral imperatives (Kant) (e.g. deception in experiments is never justified no matter what the positive contributions of knowledge) • Some deontologists are more flexible, making a distinction between harm and wrong • Harms can be compensated for but wrongs can notCodes for Ethical Decision Making • Nuremberg Code • Declaration of Helsinki • CAN Code of Ethics • American Nurses Association Code of Ethics • Code of Professional Conduct for the Nurse. Midwife, and health Visitor (UKCC)Principles of Ethical Research • Respect for Persons • Beneficience • JusticeRespect for Persons • Forms the foundation of participant's right to informed consent, privacy, & confidentiality • involves respecting autonomyor right to choose freely • right to be free from pressure or coercion • confidentiality & anonymity must be protected • must have information to make informed choices (risks vs benefits)Nonmaleficence - the duty to not inflict harm Beneficence - the duty to promote good Researcher's responsibility to minimize risk & maximize benefits to participants BeneficenceDuty to care vs Duty to advance knowledge • Research Imperative vs Therapeutic Imperative • When in doubt the therapeutic imperative must take precedence over the research imperative Justice • People ought to be treated fairly • Protection of participants from incompetence and access to research treatments are expectations of the justice principle • Random selection of participants avoids potential bias and unfairness in sample selection Methods of Protecting Human Subjects • Informed Consent • Institutional Review BoardsInformed Consent • Sufficient & appropriate information • Comprehension of information • Voluntary participation • An invitation to participate rather than an expectation Process Consent • In qualitative investigations the researcher negotiates the consent and then renegotiates the consent as unforeseen circumstances arise • The participant is part of the decision making as the study unfoldsExamples of Ethical Dilemmas • Tuskegee Syphilis Study • Willowbrook Study • AIDS ResearchRules to Protect Participants • Protect confidentiality • Do not place pressure on participants • Make participation free from harm & discomfort • Identify sponsors • Disclose the basis on which participants have been selected • Avoid hidden ID codes on questionnaires • Honor promise to provide report • Base participation on informed consent • Debrief participantsRules for Socially Responsible Nursing Research • Distinguish between science & advocacy • Do not search data in support of your views • Be aware of potential sources of bias • Represent the literature fairly • Always seek to do the best research possible • Acknowledge your sources • Seek advise on ethical issues 100%(1)100% found this document useful (1 vote)1K viewsThis document discusses ethical issues in nursing research. It outlines various codes of ethics that provide guidelines for ethical research, including protecting subjects' rights and welfar...AI-enhanced title and descriptionSaveSave Ethical issues in nursing research For Later100%100% found this document useful, undefined 1. ETHICS IN NURSING RESEARCH ASHA SEBASTIAN 1ST YEAR M.Sc. NURSING 2. INTRODUCTION Ethics is the branch of knowledge that deals with the moral principles. In any discipline that involves research with human beings or animals must address a range of ethical issues. Ethical concerns are prominent in nursing research. When human are used as study participants care must be excersiised in ensuring that the rights of those humans are protected. 3. DEFINITION Ethics in nursing research can be defined as the act of moral principles that the researcher has to follow while conducting nursing research to ensure the rights and welfare of individuals, groups or community under study. 4. IMPORTANCE OF ETHICS IN NURSING RESEARCH Nursing research usually deals with the human being, where implications of the ethics become very essential. Protect the vulnerable group and other study participants from harmful effects of the experimental interventions. Safeguard the participants from exploitation by researchers. Establish the risk benefit ratio for the study subjects. 5. Ensure the fullest respect,dignity, privacy, disclose of information, and fair treatment for the study subjects. Build the capability of subjects to accept or reject the participation in study and to have access to informed or written consent for participation in research study. 6. CODE OF ETHICS IN NURSING RESEARCH The American nurses association published the set of guidelines in 1995, ethical guidelines in the conduct, dissemination, and implementation of nursing research. Principle of beneficence This is the most important ethical principle in research, where every researcher must ensure, 7. Establishing the positive risk benefit ratio, where the risk of researcher should never exceed expected benefits for people from knowledge generated by research study. A potential risk of the research study must be carefully assessed and participants are protected from any harmful effect of the research activity. Study subjects should also be protected from expected adverse psychological consequences caused by research study. 8. Research must be conducted by a scientifically qualified expert to avoid undue discomfort or distress to study participants Participants must be provided with maximum physical, psychological, social and religious comfort, and undue disturbances and time utilization of the subject should be avoided 9. Principle of justice This principle directs the researcher to abide by the participants' right of fair treatment and maintenance of privacy The fair and nondiscriminatory selection of the participants, such as any risk benefits will be equally shared by study participants The non-prejudicial treatment of individual who decline to participate or who withdraw from the study after agreeing to participate. Anonymity of participants and confidentiality of information must be maintained 10. No information collected from study participants can be used for other than research purpose. The vulnerable subjects such as children, pregnant women, mentally ill patients, physically disabled, terminally ill and institutionalized people (prisoners) who are conveniently and easily accessible must be protected from overuse and undue use for research purpose. 11. Principle of respect for human dignity This principle of the ethics emphasizes on the freedom of choice, where participants have right to accept or reject to be a part of the research study. In addition, volunteers must be provided full information about the research study and an informed consent must be obtained, preferably a written one. 12. Participants have full right to question the researcher for an ' additional information or clarification of doubts. Participants have right to quit from the study at any stage of the research study. A fully informed consent must be taken from the participants. In case of the fetus, infant, toddler, younger child, or psychological, neurological or physical inability to give informed consent, this can be obtained from parents or legal guardians. In case of a child aged between 7 and 18 years, an assent may be obtained. 13. INFORMEDCONSENTDOCUMENT In nursing research involving human participants, the investigator must obtain the informed consent of the prospective participant. Thus, it is the responsibility of the investigator to prepare an informed consent document (1CD), which includes (a) participant information sheet (PIS) and (b) informed consent form (ICF), and get it approved by ethical committee (EC) and let each participant read the document carefully, clarify all the doubts and obtain an informed written voluntary consent from each study participant before the data collection begins in the study. If a participant is not capable of giving voluntary, the consent must be obtained from a legally acceptable/authorized representative (LAR). 14. Participant information sheet It is important for the researcher to provide complete information to the participants about the research. Informed consent must be sought only after the participant has read and understood the information provided in the PIS The content of the PIS must include, Study title and name (s) of institution (s) conducting the study. An invitation paragraph for the participant seeking voluntary consent. Name of sponsoring agency. Purposes and methods of the research study. Benefits to the participants and community. Expected duration and frequency of data collection in study. 15. Foreseeable risk, discomfort and inconvenience to the participants. Extent and way to which confidentiality of information will be maintained. Payments, reimbursement and incidental expenses to be given to participants. Provision of free treatment and/or compensation for the participants in case of research related injury. Freedom for participants to participate or withdraw from study any time. Contact details of the research team for queries related to research and chairperson/member secretary or helpline for appeal against violations of ethical principles and human rights. 16. Some additional information may be included in PIS such as alternative procedure/ course of treatment, risk of stigmatization, insurance cover related to research, foreseeable extent of information on possible current and future uses of the biological material (e.g. stored samples) and of the data to be generated from the research. At the end, the researcher may express his gratefulness for the participant's cooperation and sparing his / her valuable time and should sign the document with date. 17. Informed consent form Informed Consent Form Informed consent form (ICF) is a part of information consent document, which has declaration that I have carefully read (someone has read) to me and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this research study. I am not giving any legal right by signing this form. I will be given a copy of this form. In the end, the form has signature lines (to obtain the signature of subject and countersignature by investigator who obtained the consent). 18. Waiver of informed consent It is mandatory to obtain a voluntary informed consent from each research participant. However, researcher may apply to the Institutional Ethical Committee (IEC) for a waiver of consent if the research involves less than minimal risk to participants, emergency condition with involved risk and participants are duly protected for both privacy and confidentiality as these adversely affect the rights and welfare of participants. 19. The IEC may waive off informed consent in following situations: An emergency situation, where it is practically not possible to obtain surrogate consent. In a situation, where it is not practically possible to conduct research since confidentiality of personally identifiable information ahs to be maintained throughout research as may be required by the sensitivity of the research objective and the waiver is scientifically justified. E.g., a study on nurses' time utilization in productive and non-productive activities during working period in hospital. 20. In a situation, where research study is to be conducted on anonymized biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives, like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries, etc. In a research study, where data to be obtained from publicly available information, documents, records, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programmes for benefit of public having a bearing on public health programmes, and consumer acceptance studies. Retrospective studies, where the participants are de-identified or cannot be contacted. Certain types of public health studies/ surveillance programme evaluation studies. 21. Online /electronic consent Electronic media can be used to provide information as in the written informed consent document, which can be administered and documented using electronic informed consent systems. The process of electronic material's method of documentation must be reviewed and approved by the IEC on priority. Online consent may be obtained in research studies, which involve sensitive data such as unsafe sex, high-risk behaviour, use of contraceptives (condom, oral pills) or emergency contraceptive pills among unmarried females in India and other countries. Investigators must ensure that privacy of the participants and confidentiality of related data are maintained. 22. RESPONSIBILITIES OF AN INVESTIGATORIN OBTAINING INFORMEDCONSENT The investigator carries out following responsibilities adequately in obtaining the informed consent: Researcher should use only the Institutional Ethical Committee (IEC) approved version of information consent documents. Investigator must provide all the necessary and desired information to the participant It must be ensured by investigator that none of the participants is unduly influenced or intimidated. 23. Ensure that informed consent is obtained only after adequate information is provided to the participants. When participant or LAR are illiterate an impartial literate person, not connected to research should be present as witness. In case of differently abled participants ,use appropriate measure for better understanding Reimbursement may be given for travel and incidental expenses /participation In research after approval by the IEC. In case of institutionalized patients get consent from the head also. 24. Institutional Ethical committee Every research project must be every research project must be scientifically and ethically reviewed by ethical committee (EC)/ Institutional Ethical Committee safeguard the dignity, rights, safety and well-being of research participants. Ethical committee must have a written Standard Operating Procedure (SOP) based on the ICMR guidelines and Central Drug Standards Control Organization (CDSCO) guidelines for drug and device trials. The ethical committee should be registered with the relevant regulatory authorities, for example, ECs approving clinical trials should be registered with CDSCO, Government of India. 25. Composition of ethical committee Multi-disciplinary and multi-sectoral Equal representation of medical and nonmedical members/ technical and nontechnical members. 7-15 members 50% members of EC from outside the institute. Minimum of five members during each meeting, out of which at least one member is from outside the institute. No known record of misconduct. 26. Recommended composition of the ethical committee Chairperson: person from outside the institute. Members from basic medical sciences: 1-2. Members from clinical specialties: 1-2. Legal expert/retired judge: 1 Social scientists: 1 Lay person: 1. Member-secretary: should be from institute to conduct bbusiness of the committee 27. ICMRETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH The Indian Council of Medical Research (ICMR) brought out the 'Policy Statement on Ethical Considerations Involved in Research on Human Subjects' in 1980 Revised these guidelines in 2000 as the 'Ethical Guidelines for Biomedical Research on Human Subjects'. In 2006, a revised Ethical Guidelines for Biomedical Research on Human Participants was released. in October 2017, the revised National Ethical Guidelines for Biomedical and Health Research Involving Human Participants was released. Based on basic ethical principles, namely autonomy, beneficence, non-maleficence and justice, the new ICMR guidelines has provided the following 12 general ethical principles. 28. Principles of essentiality: By this principle the research involving the use of human participants is considered to be completely essential for the proposed research. 29. Principles of voluntariness Whereby respect for the right of the participant to agree or not to agree to participate in research or to withdraw from research at any time, is paramount. The informed consent process ensure that participants' rights are safeguarded. 30. Principles of non-exploitation Whereby research participants are equitably selected so that the benefits and burdens of the research are distributed fairy and without arbitrariness or discrimination. Sufficient safeguards to protect vulnerable groups to protect vulnerable groups should be present. Principle of social responsibility Whereby the research is planned and conducted so as to avoid creation or deepening of social and historic divisions or in anyway disturb social harmony in community relationship. 31. Principles of ensuring privacy and confidentiality By this principle the identity and records of the human participants of the research or experiment are highest kept confidential and access is limited to only those who are authorized. This cannot be disclosed without the written consent of the participants. 32. Principles of risk minimization By this principle caution and proper care is taken to ensure that the research participant are put to the minimum risk, at all levels of research and appropriate care and compensation is given if any harm occurs. 33. Principles of professional competence Whereby the research is planned, conducted, evaluated and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience and/ or training. Principle of maximization of benefit Whereby due care is taken to design and conduct the research in such a way as to directly or indirectly maximize the benefits to the research participants and/or to the society. 34. Principles of institutional arrangements Whereby institutions where the research is being conducted have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds and training oppurtunities. 35. Principles of accountability and transparency Whereby the research plan and outcomes emanating from the research are brought into the public domain through registries, reports and scientific and other publications while safeguarding the right to privacy of the participants. The research should be conducted in a fair, honest impartial and transparent manner to guarantee accountability. Related records and data notes should be retained for the required period for possible external scrutiny/audit. 36. Principles of totality of responsibility Whereby all stakeholders involved in research are responsible for their actions. The professional, social and moral responsibilities compliant with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly. Principle of environmental protection Whereby researchers are accountable for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations. 37. CODE of ETHICS FOR NURSES IN INDIA Indian Nursing Council (INC) has published the Code of Ethics for Nurses in India in the year 2000. The code of ethics for nurses is critical for building professionalism and accountability. Ethical considerations are vital in any area dealing with human beings including nursing research because they represent values, rights, and relationships. Therefore, the same code of ethics may imply for nurses dealing with human subject while conducting a research study. 38. The Code of Ethics for Nurses in India (2006) The nurse respects the uniqueness of an individual in provision of care The nurse respects the rights of individuals as partners in care and helps in making informed choices The nurse respects individuals' rights to privacy, maintains confidentiality and shares information judiciously The nurse maintains competence in order to render quality nursing care The nurse is obliged to practice within the framework of ethical, professional and legal boundaries The nurse is obliged to work harmoniously with members of the health team The nurse commits to reciprocate the trust invested in nursing profession by the society 39. ETHICAL RESPONSIBILITIES OF A NURSE RESEARCHER Ensures the respect of individuals' autonomy in consenting to participate in research and also take care for adequate protections are in place to protect study subjects from any potential harm. An adequate protection of the vulnerable group in study, such as children, elderly, pregnant women, mentally ill patients, physically disabled, terminally ill and institutionalized people, etc. 40. The nurse researcher must ensure the optimum balance between risk-benefit ratio through ensuring minimizing potential harms and to maximizing the possible benefits for all subjects enrolled in study. Maintaining competence in identified research area and to maintain proficiency in research methods 41. CONCLUSION Ethics are a fundamental part of nursing research. All nurses should have respect to the research participants, protect their rights and maintain dignity. Nurses should create a favorable environment for mutual trust and respect between the patients and rest of healthcare professionals. Ethical standards may promote the values of cooperation and collaborative work. 1 ETHICS & ETHICAL ISSUES IN NURSING PRACTICE 2 OUTLINE OF THE LECTURE Concepts of Ethics Ethical principlesEthical theories ICN & ANA code for Nurses Framework for ethical decision making Factors influencing ethical decision making Specific ethical issues related to nursing profession Boundary violations 3 INTRODUCTION Nurses who understand how patient's values and their own values shape patient – nurse interactions, and who continually develop sensitivity to the ethical dimensions of nursing practice, are best able to provide quality care and advocates for their patients. 4 DEFINITIONS VALUES ideals, beliefs, customs, modes of conduct, qualities, or goals that are highly prized or preferred by individuals, groups, or society usually not written down VALUES CLARIFICATION refers to the process of becoming more conscious of & naming what one values or considers worthy 5 DEFINITIONS VALUES CONFLICTinternal or interpersonal conflict that occurs in circumstances in which personal values are at odds with those of patients, colleagues or the institution 6 DEFINITIONS MORALS standards of right & wronglearned & internalized at early age society & culture play important role moral orientation generally based on religious beliefs MORAL VALUES preferences or dispositions reflective of right & wrong, should or should not, in human behavior 7 DEFINITIONS MORAL INTEGRITYA focal virtue that relates to soundness, reliability, wholeness, an integration of character & fidelity in adherence to moral norms sustained over time MORAL THOUGHT individual's cognitive examination of right & wrong, good & bad 8 DEFINITIONS MORAL DISTRESSthe reaction to a situation in which there are moral problems that seem to have clear solutions, yet one is unable to follow one's moral beliefs because of external restraints; this may be evidenced in anger, frustration, dissatisfaction & poor performance in the work setting 9 DEFINITIONS ETHICS declarations of what is right or wrong & what ought to be a formal process for making logical & consistent decisions based upon moral beliefs generally no system for enforcement ETHICAL PRINCIPLES basic & obvious moral truths that guide deliberation & action 10 TYPES OF ETH