DOWNLOAD PDF ETHICAL ISSUES IN HUMAN RESEARCH

Chapter 1 : Current Issues in Research Ethics : Privacy and Confidentiality

The conduct of biomedical research involving the participation of human beings implicates a variety of ethical concerns pertaining to such values as dignity, bodily integrity, autonomy, and privacy. These ethical concerns have been translated into a complex regulatory apparatus in the USA.

Vehicle identifiers and serial numbers, including license plate numbers Device identifiers and serial numbers Web Universal Resource Locators URLs Internet Protocol IP address numbers Biometric identifiers, including finger and voice prints Full-face photographic images and any comparable images Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification. A Limited Data Set is similar to the de-identified data set but has fewer of the 18 identifiers removed. The Limited Data Set is health information that may include city, state, zip code, elements of date, and other numbers, characteristics, or codes not listed as direct identifiers. Limited data sets are often utilized in multi-center studies when using fully de-identified data is not useful. The use of a Limited Data Set allows a researcher and others to have access to dates of admission and discharge, birth and death, and five-digit zip codes or other geographic subdivisions other than street address. It requires that the researcher neither re-identify the data nor contact the research participant and contains assurances that appropriate safeguards will be used to prevent improper use or disclosure of the Limited Data Set. It may, therefore, be necessary for covered entities to properly use and disclose individually identifiable health information in compliance with both sets of regulations. It is mandatory to report positive HIV test data to state health departments. Depending on the state where the research is conducted, Waivers of Authorization may not be permitted with fully identified HIV data. However, different institutions vary in their policies concerning decedent research. To use or disclose PHI of deceased persons for research, covered entities are not required to obtain an Authorization, a Waiver, an Alteration of the Authorization, or a Data Use Agreement from the personal representative or next of kin. Department of Health and Human Services Obviously, Public Health services provide important essential public health protections. Consequently, various federal and state laws, as well as the policies of various medical and healthcare professional organizations and institutions, provide confidentiality protections for adolescents. Some institutions have developed policies that would require disclosing information to parents in certain circumstances, such as in suicide research if there are threats of suicide by children, adolescents, or college students. Civil penalties usually involve monetary fines. Covered entities and individuals e. Research participants must be given fair, clear, honest explanations of what will be done with information that has been gathered about them and the extent to which confidentiality of records will be maintained. However, the promise of confidentiality cannot be absolute. Under court order or subpoena for example, there may be legal reasons for compelling a researcher to disclose the identity of, or information about, a research participant. In some instances, a researcher may be mandated to report information to government agencies as in cases of child abuse or elder abuse, certain communicable diseases, illegal drug use, and other situations such as gunshot wounds. When research is conducted across multiple sites, review how the information is being protected. Identify and limit the number of people having access to the data, particularly when data are being transferred across locations, and be aware of when data are reproduced in other formats, such as faxes or computer files. Make sure that duplicated information is properly destroyed when transferring data. Review confidentiality procedures during the continuing review of protocols by reexamining the protection of sensitive information and the success of the protection efforts. Educate researchers, research coordinators, and IRB staff on data management and data protection. Also perplexing, are situations in which the IRB must determine which safeguards should be in place to protect past participants who need to be contacted to sign a new Informed Consent Form. Behavioral and social sciences research conducted at a university that is not a covered entity may not fall under the HIPAA regulations. Protections could include the encryption of the data, authentication, and authorization of passwords for those who have access to the data, software security, and electronic and physical security of data storage devices and networks. Designing study-specific protections for confidentiality requires planning, diligence, time, and knowledge of privacy and confidentiality strategies and

procedures. It is important to develop a specific Data Protection Plan. A plan would include: A key that deciphers the code allows re-associating or linking the coded information with the identity of the participant. If applicable, codes may need to be protected by an outside agency or third party. It is important that a clear policy be defined for re-identification. Generally researchers themselves should not be able to re-identify the data but might ask a third party to trace identifiers back to the individual. Various states have laws governing the privacy of such information. Generally, state laws that provide additional privacy protections in a specific area will supercede the HIPAA regulations in those areas. State laws that require reporting of disease or injury, child abuse, elder abuse, birth, death, or public health surveillance, are not overridden by the Privacy Rule. The Uniqueness of Genetic Information There are differences of opinion about the significance of genetic information for individuals and their families. What makes genetic information unique is that it reveals information not just about the individual from whom it was collected, but also about his or her family members who may not even be aware that genetic information was gathered. It may also reveal information about the larger population of which the individual is a member. Genetic information also can be revealed about individuals and their families and populations simply from a tissue sample or database. Consequently, the decoding of the human genome makes privacy and confidentiality issues extremely acute. Medical research centers and other health care organizations will need to revise current protection procedures to avoid dignitary harms, such as stigmatization and discrimination associated with violations of genetic privacy. Policies must address challenging questions such as: This will present a significant challenge to protecting privacy and maintaining confidentiality in the collection and storage of DNA samples for pharmacogenomic research. Participants in genetic studies may not want family members to know that they carry a specific trait fearing that they will be ostracized or blamed. Furthermore, they may not want to disclose to family members the results of their genetics tests because of potential discrimination by insurance companies and concerns that test results may make the family uninsurable. Many have encouraged the U. Congress to pass a Genetic Information Nondiscrimination Bill. Researchers interested in the possibility of studying genetic markers for diseases or treatments need to learn how to plan appropriately to collect data and how to contact participants for future research and follow-up. Other considerations should include: What length of time is specified for protecting data that include linkages with names and other identifiers? What are the risks to individuals who contribute their DNA to a data repository? Who has access to a data repository? How will the genetic information be used? What are the issues in association studies and how meaningful are they? What are the appropriate safeguards for genetic information? What are the implications of state laws? How will unexpected findings e. The authors of the study concluded that genetic privacy concerns present strong deterrents to genetic counseling and testing research. Include in the Informed Consent Form any possible commercial application resulting from their genetic material for which they will not realize any profit. Protect the interlinking of databases that could reveal personal identities. Establish confidentiality and data security safeguards. Devise sound data access, ownership, and intellectual property policies. Be clear about whether and how study participants will be informed of findings that might be medically helpful to them. Arrange review and oversight by research ethics and privacy protection bodies. Many states have passed genetic privacy laws that provide protections in addition to the protections provided by federal privacy laws. Some states require informed consent and the offer of genetic counseling before performing a genetic test. Some states explicitly define genetic information as personal property; some consider DNA samples as personal property, and some states have penalties for violating genetic privacy laws. The National Conference of State Legislatures publishes information on the specific laws passed by each state. In addition, many states have passed genetic and health discrimination laws. Ethical issues in pedigree research are complicated because there can be potential conflicts between the rights and responsibilities of an individual and of a group. The privacy and autonomy of one family member can conflict with the privacy and autonomy of another individual or a family. Pedigree research relies on an accurate determination of family history, therefore, it is important to get full family participation. When publishing the family pedigree, care must be taken to protect families, especially in instances of rare diseases because these families are uniquely identifiable by the nature of their branches. There are strategies to protect identities in published pedigree diagrams such as omitting gender

information in unaffected family members, collapsing unaffected children into a single icon, and including only a portion of the family. Accessing DNA data banks and the medical histories of many people will be required to determine how genetic variation affects disease incidence, and to determine pharmacologic effects of various treatments. Finding the appropriate balance between privacy and genetic research should be continually considered as genomic medicine progresses. Ethical or IRB review of the circumstances is needed to ensure that the risks are minimized and that proper safeguards for confidentiality will be used. Researchers should consider getting informed consent in advance if there is any possibility of future use of the genetic sample. There may be instances in which prior consent for future studies is advantageous because the risk level of the future study precludes a waiver of informed consent. A brief review of some of these additional challenges is presented below to provide a more comprehensive picture of considerations needed to protect research participants. The types of mandatory reporting, and the agencies that must be reported to, vary by locality. Social and behavioral research may present dilemmas for researchers when data resulting from a behavioral study such as the use of a personality scale or depression inventory suggest that a participant might be at risk of harming himself or herself. There may be an obligation to provide ancillary care when certain diagnostic insights are realized during research. The researcher should consider that participants entrust only specific aspects of their health to the researcher, not necessarily their health in general. The researcher should consider the scope of what is entrusted to him or her by the participants, and what is his or her duty to care for their well-being. Especially in epidemiological studies, researchers often collect data from the proband the affected individual who led to the research done on their family about family members even though informed consent is provided only by the proband. When this occurs, the Common Rule applies and requires the informed consent of the third party. Generally in these situations, whenever informed consent can be sought, it is best to obtain it from the third party, depending on the urgency, practicability, and cost of obtaining it. In designing protocols, researchers must consider whether any third party may be adversely affected by the research. Several specific populations have been defined as vulnerable e. However, it is important to remember that vulnerability may apply to populations that are otherwise not viewed as vulnerable but are considered vulnerable depending on the particular research conditions. Sensitivity to being vulnerable is relative. Data considered sensitive by one person or group may not be considered sensitive by another. In addition, attitudes and vulnerabilities change over time. Many African-Americans are less trusting of medical research, given their fears of discrimination based in part on past experiences e. Gay men and lesbians also may be particularly concerned about their privacy and wary of medical research.

Chapter 2 : Stemcell Controversy | Ethical Issues in Human Stem Cell Research

Major ethical issues in conducting research Informed consent According to Armiger: "it means that a person knowingly, voluntarily and intelligently, and in a clear and manifest way, gives his consent".

This article has been cited by other articles in PMC. Abstract Legal and ethical issues form an important component of modern research, related to the subject and researcher. This article seeks to briefly review the various international guidelines and regulations that exist on issues related to informed consent, confidentiality, providing incentives and various forms of research misconduct. Researchers should note the major international guidelines and regional differences in legislation. Hence, specific ethical advice should be sought at local Ethics Review Committees. Confidentiality, ethics, informed consent, legal issues, plagiarism, professional misconduct INTRODUCTION The ethical and legal issues relating to the conduct of clinical research involving human participants had raised the concerns of policy makers, lawyers, scientists and clinicians for many years. The Declaration of Helsinki established ethical principles applied to clinical research involving human participants. The purpose of a clinical research is to systematically collect and analyse data from which conclusions are drawn, that may be generalisable, so as to improve the clinical practice and benefit patients in future. In this article, we will briefly review the legal and ethical issues pertaining to recruitment of human subjects, basic principles of informed consent and precautions to be taken during data and clinical research publications. Some of the core principles of GCP in research include defining responsibilities of sponsors, investigators, consent process monitoring and auditing procedures and protection of human subjects. Mistreatment of research subjects is considered research misconduct no ethical review approval, failure to follow approved protocol, absent or inadequate informed consent, exposure of subjects to physical or psychological harm, exposure of subjects to harm due to unacceptable research practices or failure to maintain confidentiality. As for a standard therapeutic intervention that carries certain risks, informed consent â€" that is voluntary, given freely and adequately informed â€" must be sought from participants. However, due to the research-centred, rather than patient-centred primary purpose, additional relevant information must be provided in clinical trials or research studies in informed consent form. Informed consent is documented by means of written, signed and dated informed consent form. There are also general principles regarding risk assessment, scientific requirements, research protocols and registration, function of ethics committees, use of placebo, post-trial provisions and research publication. The involvement of such populations must fulfil the requirement that they stand to benefit from the research outcome. The hierarchy of priority of the representative may be different between different countries and different regions within the same country; hence, local guidelines should be consulted. Emergency research Emergency research studies occur where potential subjects are incapacitated and unable to give informed consent acute head trauma, cardiac arrest. Where identifying information is essential for scientific purposes clinical photographs , written informed consent must be obtained and the patient must be shown the manuscript before publication. Subjects should also be informed if any potential identifiable material might be available through media access. It is imperative to obtain approval from the appropriate regulatory authorities before proceeding to any research. The constitution and the types of these bodies vary nation-wise. Avoiding bias, inappropriate research methodology, incorrect reporting and inappropriate use of information Good, well-designed studies advance medical science development. Poorly conducted studies violate the principle of justice, as there are time and resources wastage for research sponsors, researchers and subjects, and undermine the societal trust on scientific enquiry. Duplicate publication, redundant publication Publication of a paper that overlaps substantially with one already published, without reference to the previous publication. Transparent disclosure is important when submitting papers to journals to declare if the manuscript or related material has been published or submitted elsewhere, so that the editor can decide how to handle the submission or to seek further clarification. Substantial contributions to the conception of design of the work, or the acquisition, analysis or interpretation of data for the work Drafting the work or revising it critically for important intellectual content Final approval of the version to be published Agreement to be accountable for all aspects of the work in

ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Authors and researchers have an ethical obligation to ensure the accuracy, publication and dissemination of the result of research,[4] as well as disclosing to publishers relevant corrections, retractions and errata, to protect scientific integrity of published evidence. Every research study involving human subjects must be registered in a publicly accessible database e. They should have their written permission sought for their names to be published and disclose any potential conflicts of interest. Various guidelines have been formulated by organisations and authorities, which serve as a guide to promote integrity, compliance and ethical standards in the conduct of research. Fraud in research undermines the quality of establishing evidence-based medicine, and interventions should be put in place to prevent such practices. A general overview of ethical and legal principles will enable research to be conducted in accordance with the best practices. Financial support and sponsorship.

Chapter 3 : Ethical Considerations - Center for Innovation in Research and Teaching

Internet-based Research Interventions: Suggestions for Minimizing Risk MRI Research Safety and Ethics: Points to Consider (PDF file, 29 pages) Ethical Issues to Consider in Developing, Evaluating, and Conducting Research Post-Disaster.

Case 3 The atrocities committed by Nazi physicians on Jewish prisoners during World War II prompted an international tribunal, convened in the city of Nuremberg, Germany between , to elaborate 10 principles, called the Nuremberg Code, by which research involving human subjects should be governed. Publication of the Nuremburg Code in ushered in the modern era of research ethics, which mandated balancing the advancement of science with the rights and welfare of humans who serve as research subjects. Since Nuremburg, a multitude of regulations and policy statements have been developed by domestic and international bodies. Within institutions where clinical research is conducted, responsibility for the interpretation and application of these ethical principles and regulations rests with committees comprised of scientist and non-scientists, called Institutional Review Boards for the Protection of Human Subjects IRBs. General ethical principles applied to research with human subjects. The Belmont Report, which provides the ethical foundation for research regulations and guides IRB deliberations, was generated by a federally commissioned group of scientists, physicians, ethicists, and philosophers and published in The three primary ethical principles cited in Belmont are: Autonomy refers to the right of an individual to determine what activities they will or will not participate in. Implicitly, full autonomy requires that an individual be able to understand what they are being asked to do, make a reasoned judgment about the effect participation will have on them, and make a choice to participate free from coercive influence. The cornerstone of protecting autonomy is the informed consent process, whereby an investigator provides a potential research participant with full disclosure about the nature of the study, the risks, benefits and alternatives, and an extended opportunity to ask questions before deciding whether or not to participate. Populations presumed to have diminished autonomy, by virtue of impaired cognition for example, children, cognitively-impaired elderly, or mentally ill subjects or of circumstance for example prisoners or seriously ill people are considered to be vulnerable populations. In some of these cases children and prisoners special safeguards to protect their autonomy are required by regulation. Maximizing potential benefits is predicated on sound experimental design, thus research proposals must undergo rigorous scientific review before proceeding to the IRB for ethical review. Justice demands equitable selection of participants, i. The principle of justice requires that those who undertake the burdens of research must be likely to benefit from the research, and is a principle often violated by the export of clinical trials to underdeveloped countries. Designing ethical research studies. The primary concern of the investigator should be the safety of the research participant. Protecting subject safety requires the investigator to use all available information to identify potential risks to the subject, to establish means of minimizing those risks, and to continually monitor the ongoing research for adverse events experienced by subjects. The investigator must be prepared to stop the study if serious unanticipated risks are manifest. The scientific investigator must obtain informed consent from each research participant. This should be obtained in writing although oral consents are sometimes acceptable after the participant has had the opportunity to carefully consider the risks and benefits and to ask any pertinent questions. Informed consent should be seen as an ongoing process, not a single event or a mere formality. There are regulations and guidance documents that govern exceptions to the requirement to obtain informed consent, for example in cases of emergency or if the subject is unconscious and thereby unable to give consent. The investigator must consider how adverse events will be handled. In particular, it must be established a priori who will provide care for a participant injured in a study and who will pay for that care. The investigator must strive for clinical equipoise. A true null hypothesis should exist at the onset regarding the outcome of the trial, that is, if a new intervention is being tested against the currently accepted treatment, the investigator should be genuinely uncertain which approach is superior. Components of ethically valid informed consent for research. Given the appreciation that informed consent is at the crux of human subjects protection, it is not surprising that the

regulations reflect extensively upon the necessary elements of the consent document itself as well as on the informed consent process. For an informed consent to be ethically valid, the following components must be present: The informed consent document must make clear that the study is a research study, and not clinical therapy. There should also be a statement that describes procedures in place to ensure the confidentiality of data and anonymity of the participant. The informed consent document must also disclose what compensation and medical treatment are available in the case of a research-related injury. The participant must understand what has been explained and must be given the opportunity to ask questions and have them answered by someone fully conversant in the study particulars. The informed consent document must be written in lay language, avoiding any technical jargon. Consent forms for multinational research must be translated into the respective language for each participating country and back-translated to verify accuracy. Care should be taken that the consent form is administered by someone who does not hold authority over the participant. Ideally, the potential participant is given the opportunity to discuss their participation in the study with family, trusted friends, or their physician before reaching a decision. The participant must be competent to give consent. In certain emergency cases, consent may be waived due to the lack of competence of the participant and absence of an appropriate surrogate. In the event that there is a question about competence, mental status exams may be administered. If there is no need to collect personally identifiable information, and a signature on the consent form would be the only thing linking the subject to the study, an oral or implicit consent may be more appropriate. Children who cannot read or write should still signal their willingness to participate by an affirmative act for example, nodding their head. Consent by minors is referred to as assent. No informed consent may contain any exculpatory language by which the participant waives any legal rights or releases the investigator or sponsor from liability for negligence. Regulatory requirement to administer informed consent. According to the regulations at 45 CFR Clinical trials that expose subjects to more than minimal risk must be reviewed by the IRB at a convened meeting of the full Board. Minimal risk is defined as those risks and discomforts to which a person is commonly exposed in the ordinary course of daily life, including routine visits to physicians. It is important to remember that loss of privacy, i. Studies that qualify for expedited review are those that present no more than minimal risk to subjects, and involve only procedures commonly done in clinical settings, such as taking hair, saliva, excreta or small amounts of blood. A study that qualifies for expedited review is held to the same ethical standards of autonomy, beneficence and justice that are used in full board review, but the approval process may take less time. Some research with humans can be designated as exempt from IRB review. Research that is part of a routine educational experience, or in which participants will be anonymous or effectively de-identified falls into this category and may be granted a certificate of exemption. The proposal must still be reviewed by a member of the IRB to assign exempt status, but the application process may be considerably shorter. Contact the University IRB if you have questions about the category under which your study falls. Is deception of subjects allowed when doing research? As a general rule, deception is not acceptable when doing research with humans. Using deception jeopardizes the integrity of the informed consent process and could harm participants, as well as eroding trust between the public and researchers. In some instances deception is necessary to conduct the research: They will require an in-depth justification of why deception is necessary for the study and the steps that will be taken to safeguard participants, including a plan to debrief subjects at the end of the research. A form of deception of subjects can occur if the terms of the informed consent are violated by the investigator or other scientists. For example, if a subject consents to have their blood sample evaluated for markers of diabetes and the investigator or other scientists use the blood sample for purposes unrelated to diabetes research, the subject has effectively been deceived about the nature of their research participation and they have been denied autonomous agency over their own actions. The recent court case involving Arizona State University v.

Chapter 4 : Legal and ethical issues in research

However, many privacy issues are idiosyncratic to the research population, writes Susan Folkman, PhD, in "Ethics in Research with Human Participants" (APA,). For instance, researchers need to devise ways to ask whether participants are willing to talk about sensitive topics without putting them in awkward situations, say experts.

Ethical Considerations Ethical Considerations The purpose of this module is to overview ethical issues that should be considered when designing and conducting research. Describe the purpose of the the Institutional Review Board. List and explain the ethical issues that must be considered when using human subjects. Ethical considerations in research are critical. They help to determine the difference between acceptable and unacceptable behaviors. Why are ethical considerations so important in research? First, ethical standards prevent against the fabrication or falsifying of data and therefore, promote the pursuit of knowledge and truth which is the primary goal of research. Ethical behavior is also critical for collaborative work because it encourages an environment of trust, accountability, and mutual respect among researchers. This is especially important when considering issues related to data sharing, co-authorship, copyright guidelines, confidentiality, and many other issues. Researchers must also adhere to ethical standards in order for the public to support and believe in the research. The public wants to be assured that researchers followed the appropriate guidelines for issues such as human rights, animal welfare, compliance with the law, conflicts of interest, safety, health standards and so on. The handling of these ethical issues greatly impact the integrity of the research project and can affect whether or not the project receives funding. Because ethical considerations are so important in research, many professional associations and agencies have adopted codes and policies that outline ethical behavior and guide researchers. These codes address issues such as honesty, objectivity, respect for intellectual property, social responsibility, confidentiality, non-discrimination and many others. These codes and policies provide basic guidelines, but researchers will still be faced with additional issues that are not specifically addressed and this will require decision-making on the part of the researcher in order to avoid misconduct. The resources on this page address many of those issues and the case studies used in these resources provide excellent examples of these types of issues. One of the most important ethical considerations in research is the use of human subjects. To address these considerations, most institutions and organizations have developed an Institutional Review Board IRB. An IRB is a panel of people who help to ensure the safety of human subjects in research and who assist in making sure that human rights are not violated. They review the research methodology in grant proposals to assure that ethical practices are being utilized. The use of an IRB also helps to protect the institution and the researchers against potential legal implications from any behavior that may be deemed unethical. Examples of some of these issues include voluntary participation and informed consent. These principles are followed to guarantee that all human subjects are choosing to participate of their own free will and that they have been fully informed regarding the procedures of the research project and any potential risks. Ethical standards also protect the confidentiality and anonymity of the subjects. Review the following slideshow to begin understanding the key ethical considerations for researchers and the history of ethical issues in research. This slideshow is a comprehensive discussion of ethical issues that researchers may face and provides definitions of key terminology for new researchers. This slideshow includes the use of case studies to illustrate many of these considerations. The following video discusses all types of ethical considerations in research including use of human subjects, consent, plagiarism, guiding principles, and so forth. The ethics of educational research Vol. Ethical Issues in Online Course Design: Negotiating Identity, Privacy, and Ownership. Selected Papers of Internet Research, 3. Do IRBs protect human research participants?. The Journal of the American Medical Association, 10 , Research methods in social relations. Issues, Methods and Research. Ethical considerations in qualitative research. Western Journal of Nursing Research, 10 2 , Evaluating the science and ethics of research on humans:

Chapter 5 : Social Research Methods - Knowledge Base - Ethics in Research

Ethics in Research and Publication - This website is a comprehensive set of resources that are helpful in learning examining and learning about ethical issues in research. The site contains webcasts, PDFs, examples, links to other sites and numerous other resources.

Ethical considerations for qualitative research will be examined in this module. Describe why adhering to ethical principles is important in research. Explain the specific ethical issues to consider in qualitative research. Describe the purpose and function of the Institutional Review Board. Ethical considerations in research are critical. Ethics are the norms or standards for conduct that distinguish between right and wrong. They help to determine the difference between acceptable and unacceptable behaviors on the part of the researcher. Why are ethical considerations so important in research? The integrity, reliability and validity of the research findings rely heavily on adherence to ethical principles. The readers and the public wants to be assured that researchers followed the appropriate guidelines for issues such as human rights, animal welfare, compliance with the law, conflicts of interest, safety, health standards and so on. The handling of these ethical issues greatly impact the integrity of the research project and can affect whether or not the project receives funding. Because ethical considerations are so important in research, many professional associations and agencies have adopted codes and policies that outline ethical behavior and guide researchers. These codes address issues such as honesty, objectivity, respect for intellectual property, social responsibility, confidentiality, non-discrimination and many others. These codes and policies provide basic guidelines, but researchers will still be faced with additional issues that are not specifically addressed and this will require decision-making on the part of the researcher in order to avoid misconduct. The resources on this page address many of those issues and the case studies used in these resources provide excellent examples of these types of issues. Ethical issues are important in all types of research. Regardless of the type of research, the researcher should take into consideration both general research principles and those that are more specific to the type of research. In quantitative research, ethical standards prevent against such things as the fabrication or falsifying of data and therefore, promote the pursuit of knowledge and truth which is the primary goal of research. In qualitative research, ethical principles are primarily centered on protecting research participants and the guiding foundation of "do no harm". Following is a list of core ethical principles that are important in qualitative research: Respect for persons - Respect the autonomy, decision-making and dignity of participants. Beneficence - Minimizing the risks physically, psychologically and socially and maximizing the benefits to research participants. Justice - Participants should be selected from groups of people whom the research may benefit. Respect for communities - Protect and respect the values and interests of the community as a whole and protect the community from harm. One of the most important ethical considerations in qualitative research is the use of human subjects. To address these considerations, most institutions and organizations have developed an Institutional Review Board IRB. An IRB is a panel of people who help to ensure the safety of human subjects in research and who assist in making sure that human rights are not violated. They review the research methodology in grant proposals to assure that ethical practices are being utilized. The use of an IRB also helps to protect the institution and the researchers against potential legal implications from any behavior that may be deemed unethical. Examples of some of these issues include voluntary participation and informed consent. These principles are followed to guarantee that all human subjects are choosing to participate of their own free will and that they have been fully informed regarding the procedures of the research project and any potential risks. Potential participants must be competent to make a decision regarding participation and must be free from any coercion. The consent may be given in a written or oral form depending on the nature of the research. Ethical standards also protect the confidentiality and anonymity of the subjects. Researchers should not share information between participants and should have procedures in place to protect the data and names of participants. The following Slideshare presentation, Ethics in Qualitative Research, offers an overview of ethical considerations. In addition to the consideration discussed above, the presentation also addresses the ethical concerns related to "access" to research participants.

Chapter 6 : Research Ethics

When most people think of research ethics, they think about issues that arise when research involves human or animal subjects. While these issues are indeed a key part of research ethics, there are also wider issues about standards of conduct.

From the time immediately after World War II until the early s, there was a gradually developing consensus about the key ethical principles that should underlie the research endeavor. Two marker events stand out among many others as symbolic of this consensus. The Nuremberg War Crimes Trial following World War II brought to public view the ways German scientists had used captive human subjects as subjects in oftentimes gruesome experiments. In the s and s, the Tuskegee Syphilis Study involved the withholding of known effective treatment for syphilis from African-American participants who were infected. By the s, the dynamics of the situation changed. Cancer patients and persons with AIDS fought publicly with the medical research establishment about the long time needed to get approval for and complete research into potential cures for fatal diseases. After all, we would rather risk denying treatment for a while until we achieve enough confidence in a treatment, rather than run the risk of harming innocent people as in the Nuremberg and Tuskegee events. But now, those who were threatened with fatal illness were saying to the research establishment that they wanted to be test subjects, even under experimental conditions of considerable risk. You had several very vocal and articulate patient groups who wanted to be experimented on coming up against an ethical review system that was designed to protect them from being experimented on. Although the last few years in the ethics of research have been tumultuous ones, it is beginning to appear that a new consensus is evolving that involves the stakeholder groups most affected by a problem participating more actively in the formulation of guidelines for research. Ethical Issues There are a number of key phrases that describe the system of ethical protections that the contemporary social and medical research establishment have created to try to protect better the rights of their research participants. The principle of voluntary participation requires that people not be coerced into participating in research. Closely related to the notion of voluntary participation is the requirement of informed consent. Essentially, this means that prospective research participants must be fully informed about the procedures and risks involved in research and must give their consent to participate. Ethical standards also require that researchers not put participants in a situation where they might be at risk of harm as a result of their participation. Harm can be defined as both physical and psychological. There are two standards that are applied in order to help protect the privacy of research participants. Almost all research guarantees the participants confidentiality -- they are assured that identifying information will not be made available to anyone who is not directly involved in the study. The stricter standard is the principle of anonymity which essentially means that the participant will remain anonymous throughout the study -- even to the researchers themselves. Clearly, the anonymity standard is a stronger guarantee of privacy, but it is sometimes difficult to accomplish, especially in situations where participants have to be measured at multiple time points e. Good research practice often requires the use of a no-treatment control group -- a group of participants who do not get the treatment or program that is being studied. But when that treatment or program may have beneficial effects, persons assigned to the no-treatment control may feel their rights to equal access to services are being curtailed. Even when clear ethical standards and principles exist, there will be times when the need to do accurate research runs up against the rights of potential participants. No set of standards can possibly anticipate every ethical circumstance. Furthermore, there needs to be a procedure that assures that researchers will consider all relevant ethical issues in formulating research plans. To address such needs most institutions and organizations have formulated an Institutional Review Board IRB , a panel of persons who reviews grant proposals with respect to ethical implications and decides whether additional actions need to be taken to assure the safety and rights of participants. By reviewing proposals for research, IRBs also help to protect both the organization and the researcher against potential legal implications of neglecting to address important ethical issues of participants.

Chapter 7 : What Is Research Ethics? | Research www.nxgvision.com

The ethical and legal issues relating to the conduct of clinical research involving human participants had raised the concerns of policy makers, lawyers, scientists and clinicians for many years. The Declaration of Helsinki established ethical principles applied to clinical research involving human participants.

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Chapter 8 : Ethical Issues of Research with Human Subjects | Nurse Key

Ethical issues in human research generally arise in relation to population groups that are vulnerable to abuse. For example, much of the ethically dubious research conducted in poor countries would not occur were the level of medical care not so limited.

We know about some of the unconscionable violations of human rights that have been perpetrated in the name of research, and it is reasonable to assume that many more violations remain unknown. In the infamous Tuskegee experiment, the U. Public Health Service conducted research for many years on the effects of not treating syphilis in African American men. The participants in that study were led to believe that they were receiving treatment, and the researchers even tried to prevent the participants from receiving treatment for syphilis from any other health care provider Brandt, In the aftermath of World War II, the public became aware of horrendous medical experiments performed by Nazi doctors, including testing drugs for immunization against smallpox, cholera, and malaria. The postwar military tribunal found that performing medical experiments without consent of the subjects constituted war crimes and crimes against humanity. The tribunal sentenced eight doctors to prison and seven doctors to death. In addition, the tribunal issued the Nuremberg Code, which states the basic requirement of voluntary consent by human subjects of research. More recently, the increase in the volume of research performed in developing countries and the persistence or worsening of health disparities have led to an increased concern with issues of social justice in research with human subjects. In , the U. This influential report identifies three basic ethical principles for research with human subjects: In recent years the Belmont Report has been critiqued on a variety of grounds see, for example, Childress and others, , but it remains an extremely important resource in the field of research ethics. In addition, the three principles of the Belmont Report provide a convenient way to categorize and analyze the wide range of issues that arise in research on human subjects. The principle of respect for persons encompasses informed consent to participation in research. The principle of beneficence includes balancing the benefits and risks of research. The principle of justice prohibits exploitation of subjects and communities and requires fairness in selecting or excluding potential subjects of research. After analyzing each of these three basic principles, this chapter will evaluate different approaches to two specific issues. The second issue is clarifying the ethical duty that researchers have to their human subjects after completion of the research, particularly when research is performed in developing countries by researchers from developed countries. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: Respect for persons incorporates at least two ethical convictions: The principle of respect for persons thus divides into two separate moral requirements: In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children.

Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving childrenâ€”even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices. Who ought to receive the benefits of research and bear its burdens? Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are 1 to each person an equal share, 2 to each person according to individual need, 3 to each person according to individual effort, 4 to each person according to societal contribution, and 5 to each person according to merit. Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the s, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available. Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes e. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research. Applications Applications of the general principles to the conduct of research leads to consideration of the following requirements: Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied. While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc Comprehension. The manner and context in which information is conveyed is as important as the information itself. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension. Special provision may need to be made when comprehension is severely limitedâ€”for example, by conditions of immaturity or mental disability Voluntariness. An agreement to participate in research constitutes a valid

consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable. Unjustifiable pressures usually occur when persons in positions of authority or commanding influenceâ€"especially where possible sanctions are involvedâ€"urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. Assessment of Risks and Benefits. The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate. The Nature and Scope of Risks and Benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked The Systematic Assessment of Risks and Benefits. Justice is relevant to the selection of subjects of research at two levels: Individual justice in the selection of subjects would require that researchers exhibit fairness: Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects e. Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus, injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs [institutional review boards] are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects One special instance of injustice results from the involvement of vulnerable subjects.

Chapter 9 : Ethical Considerations in Research on Human Development and Culture - Oxford Handbooks

Education in research ethics is can help people get a better understanding of ethical standards, policies, and issues and improve ethical judgment and decision making. Many of the deviations that occur in research may occur because researchers simply do not know or have never thought seriously about some of the ethical norms of research.

Research ethics involve requirements on daily work, the protection of dignity of subjects and the publication of the information in the research. However, when nurses participate in research they have to cope with three value systems; society; nursing and science which may be in conflict with the values of subjects, communities, and societies and create tensions and dilemmas in nursing. Using the Medline and the Nursing Cinahl data base, the most important ethical issues which appear in bibliography, will be addressed. After a short description of the nature of nursing, and the advocacy role of nurses, the writer will attempt to highlight the possible conflicts that nurses have to deal with, when undertaking or participating in research. The major ethical issues in conducting research are: However, both the nature of nursing which focuses on caring, preventing harm and protecting dignity and the advocates role of nurses which calls for defending the rights of subjects, are sometimes incongruent with the ethics in research. Ethical issues, conflicting values, and ambiguity in decision making, are recurrently emerging from literature review on nursing research. Because of lack of clarity in ethical standards, nurses must develop an awareness of these issues and an effective framework to deal with problems involving human rights. Keywords Research ethics, moral dilemmas in research, nature of nursing, nursing research, nursing advocacy Introduction Ethics is rooted in the ancient Greek philosophical inquiry of moral life. It refers to a system of principles which can critically change previous considerations about choices and actions. Scientific research work, as all human activities, is governed by individual, community and social values. However, when nurses participate in research they have to cope with three value systems; society; nursing and science. According to Clarke these values may conflict with the values of subjects, communities, and societies and create tensions and dilemmas in nursing. Historical overview- Ethical codes Human experimentation has been conducted even before 18th century. Professional codes and laws were introduced since then in order to prevent scientific abuses of human lives. This code focuses on voluntary informed consent, liberty of withdrawal from research, protection from physical and mental harm, or suffering and death. It also emphasises the risk- benefit balance. It was only in with the declaration of Helsinki that the need for non therapeutic research was initiated. Since then there has been a significant development of professional codes in conduct and research. Beauchamp and Childress define autonomy as the ability for self determination in action according to a personal plan. It also seeks to prevent assaults on the integrity of the patient and protect personal liberty and veracity. In this study, rural black men were chosen as subjects in a study of syphilis. Although a cure for syphilis was found after the start of the study, it was decided not to treat them and they had not been told that penicillin was effective to their disease. He must also provide a "Noncoersive Disclaimer" which states that participation is voluntary and no penalties are involved in refusal to participate. The researcher must also take into account that persons with physical, cultural and emotional barriers may require a very simple language in order to understand him. The Declaration of Helsinki provide some help as it declares that the interest of the subject must always prevail over the interests of society and science. Another major ethical issue is obtaining an informed consent from groups with diminished autonomy which will be further discussed later. From what has been discussed, it becomes clear that disclosure, comprehension, competency and voluntariness are the four essential parts of a consent. Beauchamp and Childress, suggest that "the principle of beneficence includes the professional mandate to do effective and significant research so as to better serve and promote the welfare of our constituents". Carr says that if the research findings prove that it was not beneficial as it s expected, this can raise immense ethical considerations especially for nurses. According to Burns and Grove "discomfort and harm can be physiological, emotional, social and economic in nature". A researcher must consider all possible consequences of the research and balance the risks with proportionate benefit. The type, degree, and number of potential risks must be assessed as well as the patients value system which ranks various harms. If the risks

outweigh the benefits, the study should be revised. Treece and Treece say that debriefing refers to explaining the exact aim of the study and why the disclosure was not full. Clarke addresses the ethical dilemma of the researcher when confidentiality must be broken because of the moral duty to protect society. On the other hand, the deontological theory which ignores the result implies that the moral duty is what really matters. If a researcher, though, acts deontologically he may feel that he has not protected society. Another issue is that the researcher may have to report confidential information to courts which can also cause moral dilemmas. In that cases it can be argued that the moral duty and personal ethos can be stronger than legal requirements. Ford and Reutter suggest using pseudonyms and distorting identifying details of interviews when transcribing the tapes used. Department of Health and Human Services DHHS may be useful to help ensure the privacy of research participants especially in studies in which participants and researchers may be exposed to compelled legal disclosure of research data. The researchers must always bear in mind all psychological and social implications that a breach of confidentiality may have on subjects. In order to protect participants, they have to inform them on their rights, and use all possible coding systems that they regard appropriate in each case. A researcher cannot decide on behalf of other persons on those delicate issues. All aims, instruments and methodology must be discussed with the prospective subject and the research workers prior to the investigation. Treece and Treece suggest that whenever subjects refuse to report personal information as they regard it an invasion of privacy, the researcher ought to respect their views. They also imply that privacy can be invaded when researchers study certain groups without their knowledge and without identifying themselves. The different opinions about their participation in research can be attributed to their inability to give an informed consent and also to their need for further protection and sensitivity from the researcher as they are in a greater risk of being deceived, threatened or forced to participate. Many are in favour of the use of such subjects in research whilst others would argue strongly against it. Most condition their responses according to the seriousness of the research, the level of potential risk and the availability of alternatives. In the case of mentally ill, family as well as employers and colleagues have the right to know while patients may not be able to see the testimony of others in their own record. In the case of mentally ill patients, it is important to measure comprehension and develop valid tools for it, before obtaining informed consent to participate in a research study. In a descriptive study of Beebe and Smith the Evaluation to Sign Consent ESC form was used in order to document comprehension in 29 schizophrenia outpatients. Participants prescribed two antipsychotic medications were significantly more likely to require a prompt than those prescribed only one antipsychotic. According to Lasagna there are strong feelings among professionals who disagree with experimentation on vulnerable groups. Skills of the researcher Jameton declares that in research the three more important elements are the competency of the researcher, the careful design, and worthwhile expected outcomes. Any lack of knowledge in the area under research must be clearly stated. Inexperienced researchers should work under qualified supervision which has to be reviewed by an ethics committee. The choice depends on the object of the study. When human beings are involved, all the ethical issues, discussed above, must be taken into account. Raya focuses on the unique element of caring in nursing while Swanson views Nursing in the same scope as "informed caring for the wellbeing of others". Swanson suggests that nursing has to do with "science, concern for humanity and caring. Mayeroff describes caring as an interaction which offers space for personal growth for both the carer and the cared. Doing for, means predicting individual needs, encouraging, performing tasks with adequate skills and competence, protecting the patient from harm and preserving the dignity. On the other hand, enabling, means enhancing self-care by training, informing and explaining to the patient as well as assisting with finding alternatives. Other professions can also claim that caring is an important part of their practice. It can not be stated either that all nursing procedures include caring. The vulnerability of the sick and the lack of patient participation in health care, creates a danger of patient exploitation by nurses. The rapid change and development of nursing emerged the need for a code of professional conduct to guide nurses in their practice. Advocacy in nursing Advocacy primarily used in legal contexts, refers to the protection of human rights of people who cannot defend them for themselves. The rights protection model implies that nurses helps persons to understand and exercise their rights. They also aim to protect and enhance personal autonomy. Last, the respect for persons model focuses on human dignity,

privacy and selfdetermined choices that the nurse has to protect if the person is not autonomous or self-determining. According to Johnstone all professions with a morally significant relationship with a patient ought to fulfil the role of the advocate. Conflicts in nurses Beneficence-Non malificence A common feature in professional conduct codes and those specific to research is the principle of non-malificence. The ANA Code of conduct declares that the nurse protects the clients and the public from unethical, incompetent or illegal practice of any person. Even if nurses are certain about the incompetence of the investigator, which is usually very difficult, they have to deal with serious dilemmas. First they have to consider the fact that if patient learn that they are exposed to professional misconduct, they may lose faith in health care. Jameton though, believes that patient should be informed as they will appreciate the trust shown to him by frankness. However, even if nurses decide that their duty of caring and being loyal to the patient is more important, they may have to deal with the hierarchical and bureaucratic systems of institutions which demand loyalty to subordinates to the institution. In case the incompetent researcher is a higher status professional, nurses may be obliged to show loyalty, but this can conflict with loyalty to patients. Consequently, nurses may feel that their patients are vulnerable and exposed and that they can not prevent it because they do not have a voice or power to resist. This is merely why many authors believe that it may not be possible for nurses to act as advocates of subjects in research. According to the Belmond commission the general aim of practice is to enhance the well being of individuals while the purpose of research is to contribute to general knowledge. This distinction highlights the differences in the aims of a nurse practitioner and a researcher. It is therefore very difficult for nurses to be engaged in studies whose aim is not directly beneficial to the subject. They must though, consider that these studies may generate and refine nursing knowledge. Another problem that nurses may have to face is taking part in randomised control trials. According to Brink and Wood dedicated nurses are finding themselves under pressure when they are asked to exclude some patients from an obvious beneficial treatment such as relaxation techniques for relief of post operative pain. Skodol Wilson implies that there should be some provisions for alternative effective care. In order to prevent human exploitation, ethics committees were introduced. If instead of the patient and his needs, the central aims of the committee are personal interests, profits and academic prestige, then nurses will have none to share their concerns with, and deal with their dilemmas in research. Confidentiality The issue of confidentiality which is stated as very important in the Hippocratic oath, is another possible issue of conflict for nurses either as practitioners or researchers. Clause 10 of the ICN Code for nurses emphasises that all information obtained during nursing practice should be kept secret apart from cases that it should be reported in a court, or in cases that the interests of society are important. It is important therefore, to seek advice in ethics committees to get approval for disseminating the results of the data collection including an account of what happened. The trust showed to them must not be jeopardised. Patients reveal information concerning their body and mind and expect them to be used only in a therapeutic manner. When dilemmas according to confidentiality arise, trust as a basic element of a therapeutic relationship should be considered and maintained.