Human Biological Materials in Research: Ethical Issues and the Role of Stewardship in Minimizing Research Risks

Recent scientific and technologic advances generated from the human genome project have increased the ability of researchers to study human biological materials. This has enhanced the ease with which highly personal information such as genetic makeup can be revealed about individuals, families, and communities. In addition, a change in the societal value of human biological tissue from waste to commercial resource has occurred. A new model of stewardship is developed that can be used as a guide for protecting human research participants who are involved in studies that include collecting and handling human biological samples. Nursing implications to ensure protection of human research participants are discussed. Key words: *ethical decision making, genetics, institutional review, nursing ethics, protection of human subjects*

Brenda Recchia Jeffers, PhD, RN
Associate Professor
Mennonite College of Nursing
Illinois State University
Normal, Illinois

THE EXPLOSION of research and technology that has accompanied the human genome project necessitates examining the impact of these developments on research risks and the ethical treatment of research participants in studies using human tissue samples and biological materials as the unit of data analysis. Because of techniques that enable extraction of DNA from minute biological samples, genetic tests potentially can be performed on any tissue sample collected and stored.[1] According to estimates from the National Bioethics Advisory Commission,[2] there are more than 282 million human biological specimens housed in laboratories, tissue repositories, DNA banks, and medical centers across the United States. The number of specimens stored is expected to increase by tens of millions over the next decade.[2] The collection,

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use, and storage of human biological materials for research raises numerous ethical questions regarding the provision of informed consent, the danger of violations in genetic and medical privacy,[3,4] and adequate disclosure of relevant risks and benefits to those individuals who provided the biological material, often without their knowledge regarding its intended use.

Nurses in their research roles as principal investigators, collaborators, coordinators, and Institutional Review Board (IRB) members have a significant impact on the design and conduct of research studies. Nurses serve as advocates for the protection of individuals involved in research and have been influential in stopping research when breaches in approved protocols have jeopardized the safety of research participants.[5] However, few articles have been published in nursing journals that address the ethical issues that arise when using human biological materials in research. This article defines the characteristics of human biological materials, identifies and examines research risks involved in the protection of human subjects when human biological materials are used in genetic research, and identifies key ethical issues that have led to conflicts between participants and investigators. A model of stewardship is developed that addresses these ethical conflicts and is advanced as a new framework to guide ethical decision making in research using human biological materials.

THE NATURE OF HUMAN BIOLOGICAL MATERIALS

Human biological materials have been collected for decades. These materials are used for many reasons, such as diagnosis and treatment of disease, quality control in pathology laboratories, medical and biological research, health care personnel education, and forensic evaluation.[1,6] Examples of human biological materials used by researchers and health care personnel include cells, tissues (bone, muscle, connective tissue, skin), organs, blood, fetal tissues, wastes (urine, feces, shed placenta, hair clippings), and subcellular materials such as DNA.[1] Most of these materials are stored in hospitals, national tissue banks, or the growing number of DNA banks.[7] These materials have been used consistently by researchers interested in genetic research and have served as a source of samples from individuals who have not always given explicit consent for their use in research.

Genetic research depends on the accessibility of tissue and cell samples. Genetic researchers use human biological material to study human genetic variation; locate genes and gene markers that are associated with disease; and increase understanding of the interaction between genes, environment, and lifestyle in onset of disease. An increasingly common use for these materials is the development of commercial products such as genetically tailored drug development or identification of genes that may be patented for future use in gene therapy.[2]

COLLECTION AND STORAGE OF HUMAN BIOLOGICAL MATERIALS

In some cases, specific informed consent is obtained for the collection, storage, and use of the sample in research. In other situations, no type of informed consent is obtained, and the specimen is collected during routine medical or surgical procedures. Many times individuals give consent for the collection of a tissue sample as a part of a routine surgical consent but have no knowledge regarding the

storage of the material or that it may be used in future research.[8] The National Bioethics Advisory Commission[2] identified and categorized human biological materials that are available for clinical or research purposes and identified the type of personal information that is associated with each category (see the box entitled "Categories of Human Biological Materials").

CONCERNS ABOUT THE CURRENT USE OF BIOLOGICAL MATERIALS IN GENETIC RESEARCH

The risks inherent in the collection and storage of tissue samples and their subsequent use in genetic research are receiving renewed attention.[2,9–11] Although researchers typically have relied on tissue repositories, DNA banks, and the collection of tissue specimens during routine procedures to supply them with samples for use in research, the ethical implications of this process are being scrutinized more closely. The genetic technology explosion and the speed, ease, and accuracy with which genetic information can be generated are impacting the conception of research risks present in tissue collection and use. For example, recent developments in bioinformatic computer software programs have allowed genetic researchers to rapidly search, analyze, and generate DNA sequences. Using the World Wide Web, genetic researchers can easily share information with colleagues across the world.[12]

Categories of Human Biological Materials

REPOSITORY COLLECTIONS

Unidentified specimens: Identifiable personal information not collected or if collected not maintained or retrievable.

Identified specimens: Specimens linked to personal information such as name, patient number or relationship to a family member whose identity is known.

RESEARCH SAMPLES

Unidentified samples: Samples supplied from a repository from a collection of unidentified human biological specimens. Sometimes called "anonymous."

Unlinked samples: Samples lack identifiers or codes that can link sample to an identified specimen or particular human being. Sometimes called "anonymized."

Coded samples: Samples are from identified specimens with a code. Sometimes called "linked" or "identifiable."

Identified samples: Personal identifiers such as a name or patient number allows linking the biological information directly to the individual.

Source: Reprinted from *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance,* National Bioethics Advisory Commission, 1999, National Bioethics Advisory Commission.

Genetic information has social value. Research risks traditionally associated with social science research are of primary consideration when designing research protocols using human biological materials. Issues of privacy and confidentiality, the possibility of stigmatization of individuals, families and communities that share the same genetic makeup, an informed consent process that may span several years into the future, and commercialization of donated human biological material are research risks that must be addressed when human materials are used in research (Table 1). These concerns contribute to an expanded model of risk research.

Families and communities as human subjects

Information revealed as a result of genetic research can greatly benefit research participants by identifying risks for developing disease. This may allow the individual to take action to avert or lessen the impact of the disease effects.[13] At the same time, the diagnostic capabilities of genetic analysis can expose the individual to increased social risk or stigmatization that may extend to families and communities that share the same genetic makeup. Because genetic information is shared among family members, families and communities share in any social or psychological risks that may result from the generation of genetic research findings; however, they historically have not been part of the informed consent process. Glass[14] argues that a paradigm shift is occurring that obligates researchers to move away from a traditional investigator/research participant relationship to an investigator/research participant/family/community relationship. Genetic information revealed about individuals and families also may reveal information about

Table 1. Risks to participants donating human biological material for genetic research

Elements of risk	Existing elements of research risk	Emerging elements of risk in genetic research
Human subject	Researcher-participant dyad	Researcher-participant-family-community
	Participant bears risk	Families and communities bear risk
Privacy and confidentiality	Risk primarily psychosocial in nature	Economic risk in the form of employment or insurance discrimination
Informed consent	Consent for known data collection period and known research uses	Multiple and unknown data collection periods for unknown research uses
Human biological sample	Biological material as waste	Biological material as economic resource
	Value in the generation of shared scientific knowledge	Commercial commodity

Genetic information revealed about individuals and families also may reveal information about the genetic makeup of entire communities.

the genetic makeup of entire communities. In Iceland, the biotechnology company deCODE Genetics is collecting DNA samples from large numbers of people for genetic analysis. The relatively isolated genetic pool of the Icelandic population allows researchers to isolate genes or genetic markers that cause or increase susceptibility to disease. The risks of a private company collecting and having access to the DNA of large numbers of Icelanders have caused considerable debate.[15] Identification of genes or genetic markers that identify genetic susceptibility to disease in an individual and that generate negative perceptions or labeling poses the risk of stigmatization to persons or groups.[2] Although entire families or communities may be affected by research findings and share in the risks of genetic research, they are involved and share in this risk without explicit consent. Today, families as well as communities are beginning to express an interest in dictating what can be done with a donated tissue or cell sample.[16]

Privacy and confidentiality

In genetic research, violations of privacy and confidentiality may have severe economic or occupational consequences. Third parties, such as employers or insurers, may have an interest in genetic information about individuals, families, and groups in order to determine an individual's ability to perform a job or the possibility of developing a costly future illness. Minimizing research participants' risks to breaches in privacy and confidentiality is always a concern for researchers. However, misuses of genetic information have severe consequences that can threaten a participant's economic well-being. The possibilities of employment or insurance discrimination make it necessary for researchers to develop methods to address this danger. For example, the setting and purpose of the collection of human biological material will influence the degree of risk to the individual.[2] Blood collected in the workplace to detect genetic disease markers that may impair an individual's ability to work exposes the participant to a high risk of workplace discrimination. Even if the only outcome of a breach in privacy results in embarrassment, having intimate information disclosed to others can be demeaning and closely connected with cultural views of unnecessary exposure of the body to others.[2]

Informed consent

Obtaining informed consent is more difficult when stored tissue is used for multiple research studies that occur at unknown future collection periods. For example, consents for DNA sampling often ask participants whether they wish to be informed about health risks or benefits that may become available as a result of future studies using their DNA sample. Roy et al[4] state that asking individuals to specify in the present what they want to be informed about in the future, without any idea of what the risks and benefits of the information will be to them, is contrary to normative ethical views of informed consent. Another issue related to DNA sampling identified by McEwen and Reilly[7] is the possible objection of participants to the use of DNA sam-

ples for future research that does not directly benefit themselves or their family members.

Human biological sample

Isolating disease-causing genes and patenting cell lines are of tremendous commercial value to pharmaceutical companies and venture capitalists. In the past, most human biological material has been considered a type of waste, with no meaningful significance to the individual donating the material. However, the increasing economic value of human biological material has resulted in tissue samples and biological materials being described as a "hot clinical property," a "treasure trove," or a "gold mine." The differences in meaning of body tissue to researchers and to those contributing the tissue must be of ethical concern to researchers. Contribution of one's biological material does not imply that what is being contributed has no value to the contributor.[17] Andrews and Nelkin point out that the conditions that exist and guide the handling and use of body tissue reflect community ideals of altruism and gift giving: "Giving blood and body tissue rather than selling it, for example, is a way to encourage altruism and to affirm social cohesion by linking donors to strangers and donations to the public good."[18(p55)] Campbell[17] states that when individuals agree to organ or tissue donation, the recipient has a responsibility to serve as the trustee of the tissue and to ensure protection of the contribution. In addition, body parts, tissues, and organs can shape our sense of self and have symbolic significance. Ethical conflicts arise when the motivation of the biological material donor is one of promoting the public good and the researcher's motive for collection is one of ownership and anticipated private commercialization.

Identification of risks in research involving human biological material

Possible research risks must be identified to ensure protection of human participants. The existing ethical principles that serve as a framework to guide research—respect for human dignity, beneficence, and justice—were first articulated in *The Belmont Report*,[19] and they have been used successfully by investigators and reviewers to protect individual participants in research. Recently, however, these principles have been less successful in addressing emerging research risks to individuals and groups donating human biological material for research, and ethical conflicts have arisen.

Critical ethical conflicts in the use of human biological materials in research

When the participant and researcher enter into an agreement with conflicting motives and intents, a sense of betrayal can occur. Ignoring the values and concerns of individuals and communities that donate human biological material has led to legal action in the United States. Recently, Jewish families whose children died from Canavan disease willingly contributed blood and tissue after their children's deaths to researchers interested in developing a prenatal test for this genetic neurologic disease. After researchers developed a prenatal test for the genetic disease, the Canavan Foundation was forced to stop offering free genetic screening after it was advised that it would have to pay royalties and comply with licensing terms to the researcher and hospital where the test was developed. Both the foundation and the families participating in the research have

brought legal action charging that researchers are trying to profit from their children's illnesses and are hindering other children's access to the test. One of the fathers who provided blood and tissue to researchers after the death of his two children stated, "What the hospital has done is a desecration of the good that has come from our children's short lives."[20(p47)]

A new approach to thinking about risks to research participants donating human biological materials is needed that can allow advancement of research, incorporate social and cultural concerns, and address the emerging and expanded elements of risk in genetic research.

A STEWARDSHIP MODEL TO GUIDE RESEARCH USING HUMAN BIOLOGICAL MATERIALS

The emerging elements of research risks in genetic research using human biological material necessitate the development of a new model that can guide ethical action and ensure protection of participants. Stewardship is a concept that has been used in bioethical literature to discuss treatment and care of human life,[21] in the nursing literature to organize management and leadership principles,[22,23] and in biology literature to discuss environmental resources.[24] More recently, pathologists have used the concept to discuss their role in protecting unauthorized release of human tissue stored in the laboratory.[6] The concept of stewardship is used in this article to develop and advance a new model that can serve as a framework to guide ethical decision making and decrease ethical conflicts presented by the emerging ethical challenges of research using human biological samples. Investigators, collaborators, research reviewers, data collectors, and all involved in the conduct of research protocols have a role as stewards of the materials or resources entrusted to them (Fig 1).

Ethical principles underlying stewardship

The emerging elements of research risk in studies using human biological materials for genetic research, such as family risk, economic harm or discrimination, and commodification of biological samples, raise ethical issues not easily addressed by the traditional principles articulated in *The Belmont Report.* However, an emerging international consensus has identified four useful ethical principles to guide research in genetics. These general principles are: (1) recognition of the human genome as a part of the common heritage of humanity; (2) upholding international human rights; (3) respect for the values, traditions, culture, and integrity of the research participant; and (4) acceptance and upholding of human dignity and freedom.[4] These international principles frame research in genetics within the greater context of community and obligate the researcher to demonstrate respect for the values, traditions, and culture of the participant.

Whereas the ethical principles of *The Belmont Report* emphasize individual self-determination and autonomy, the international ethical principles guiding genetic research emphasize the social nature of research participants and the shared common humanity of researcher and research participants. Recognition that the human genome is a part of the common heritage of humanity obligates the researcher to consider the interests of not only the individual, but also the larger community and culture of the research participant. Roy et al[4] state that in order to facilitate ethical decision making in genetics

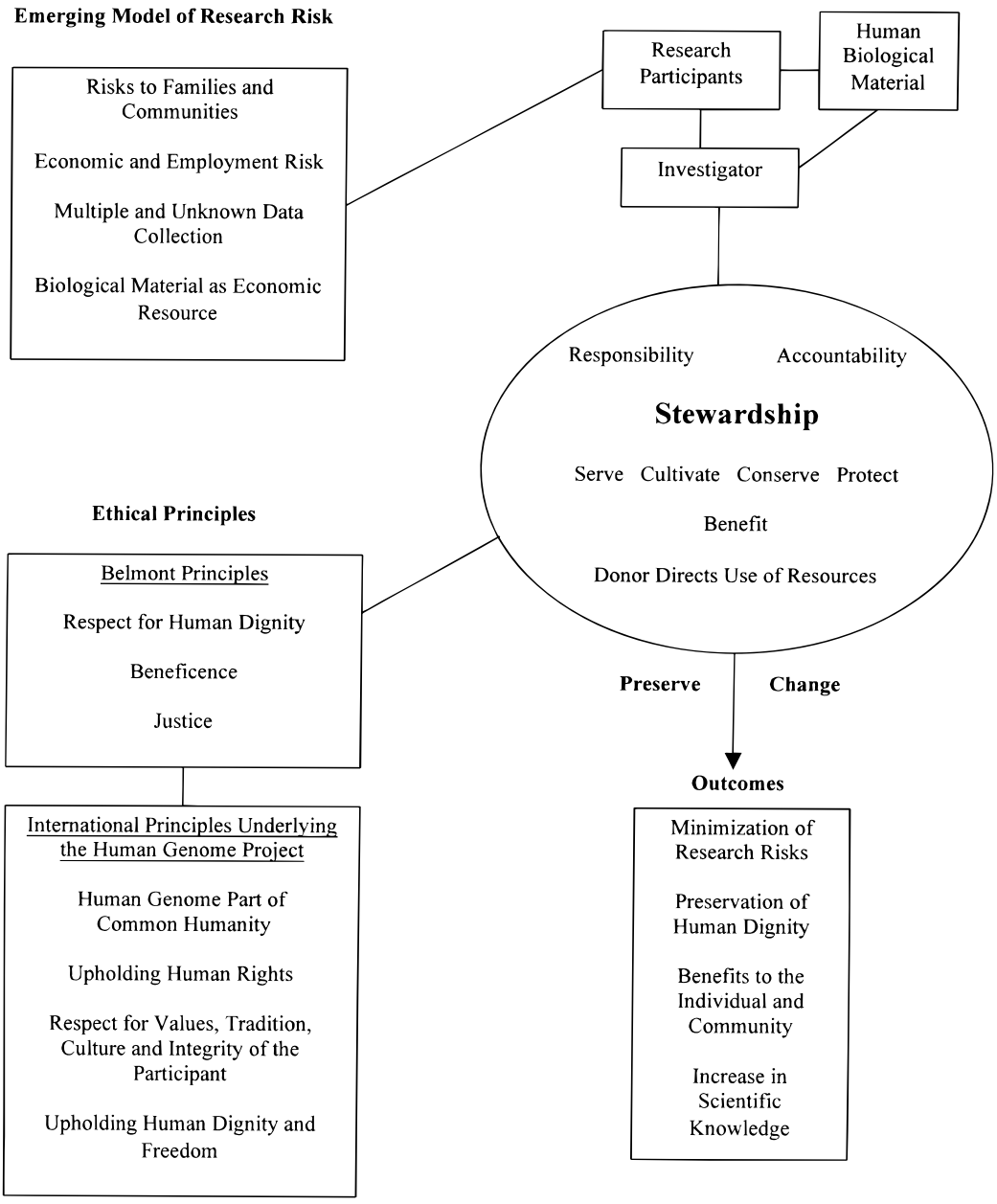

Fig 1. Stewardship model to guide research using human biological material.

and genetic research, a normative framework is needed to bring together the traditional ethical principles of research and the international ethical principles of the human genome project. The stewardship model connects these two sets of ethical principles and assists researchers in simultaneously applying the two ethical frameworks.

Characteristics of stewardship

Stewardship arises from a respect for human dignity and a recognition of a common humanity.[21] This foundation is crucial in understanding the role stewardship can have as a framework to unite traditional ethical principles that emphasize respect for autonomy and the international principles that recognize the social nature of the individual situated within a community, tradition, and culture. Characteristics of stewardship include the responsible use of resources, accountability for the well-being of another, and service to others.[25] The steward acts to benefit others with an awareness that what is stewarded is something of value.

Responsibility, accountability, and service

Stewardship in the collection, storage, and use of human biological materials seeks human dignity within the context of the common good and implies upholding the values of the donor. The researcher acts as a representative with responsibility for the one who has true ownership to serve, protect, conserve, and benefit the donor of the human biological material. The model directs investigators to make research and design protocol decisions that serve the interests of donors and their community by considering community, social, and personal understandings of the body. Stewardship establishes a responsibility on the part of the researcher to return a benefit to those individuals, families, and communities donating the sample.

Stewardship arises from a respect for human dignity and a recognition of a common humanity.

Cultivate, conserve, and protect

A paradox of stewardship is that cultivating what is stewarded results in both change and preservation.[24] In the stewardship model, the investigator serves as a representative for the one who has true ownership and acts not just as the custodian of the biological materials, but as a cultivator of what is stewarded. Using a model of stewardship to guide the ethical conduct of research using human biological materials obligates the researcher to conserve the donor's values, traditions, and culture in ethical decision making. Stewardship recognizes the importance of not only preserving the human dignity of individual research participants, but also changing what is stewarded to benefit the community of the participant. The change that occurs within a stewardship model increases the value of what is stewarded in order to achieve the outcomes of preservation of human dignity and benefit for the common good.[21,24,26] It does not rule out possible benefits to the individual donating the material or the steward; however, the primary obligation of the steward is to improve what is given for the common good.[24] The emphasis is protection of entrusted resources to serve common humanity.

Benefit

The steward is obligated to ensure that change results in an outcome that is beneficial not only to the individual, but also to the common good. This process of change is an integral part of the stewardship model and fosters scientific research by obligating the steward to manage and increase the value of resources that are stewarded.[24]

Components of the stewardship model

A basic assumption of the stewardship model (see Fig 1) is that human biological materials are resources donated by research participants. In this model, the steward of the resources, or the investigator, assumes responsibility for the donor's intent, the manner in which the resources are used, and the outcomes that will result from their use. Key elements of the stewardship model include balancing the preservation and conservation of human dignity while allowing change and taking action to increase the value of what is preserved. Outcomes of the stewardship model include preservation of human dignity, use of resources to benefit the individual and community, and use of donated human biological resources to increase scientific knowledge. The stewardship model introduced in this article can be applied to minimize research risks emerging in the literature (Table 1) while incorporating the traditional Belmont ethical principles and international ethical principles underlying the human genome project.

Application of the stewardship model in research using human biological materials

Minimizing risks to families and communities as human subjects

Recognizing that groups such as families and communities share in the risks of research with human biological materials and using the stewardship model to direct action, guides investigators to develop mechanisms to incorporate community and personal understandings of donation of biological materials. Although mechanisms for individuals and groups to voice their concerns may be difficult for investigators using stored materials, ongoing debates and public discussions could be instituted similar to a system recently established in the United Kingdom. Milewa and Calnan[27] report that a human genetics commission was established to allow a means for the public's concerns on biotechnology issues to be heard at the grassroots level. The ability of those outside the scientific community to influence decision making related to genetic research and the application of research findings is a step toward greater accountability for investigators and greater participation of groups and communities.[27]

For genetic epidemiologic studies involving the collection and use of human biological materials from existing communities, extensive involvement of the community should become part of the research protocol. An example of this type of involvement is the document developed by the Australia National Health and Medical Research Council (NHMRC). It contains detailed procedures for working with the aboriginal communities in Australia and involves community representatives in all aspects of the research project from preparation of the research proposal to review of research findings before publication.[28] Questions remain, however, regarding a clear definition of community and how best to resolve conflicts between individuals' and communities' desires for participation in research protocols that collect human biological materials.

Minimizing risks to privacy and confidentiality

Applying the stewardship model to risks of privacy and confidentiality that arise in research using human biological materials places the responsibility on the investigator to guard the release of study findings to any third party. The investigator acts to benefit

those who have donated biological material and has a responsibility to serve those who have donated. The application of scientific knowledge generated from the willing donation of a research participant must have the interest of the donor as its primary concern. Both publicly and privately funded researchers can obtain certificates of confidentiality to protect the release of information that may lead to discrimination or stigmatization.[29] An additional concern is that donors who gain knowledge from genetic research regarding their genetic makeup or genetic susceptibility to disease may be penalized if they are required to share this information with employers or insurance companies. Federal policies that extend to both publicly and privately funded research must be enacted to protect research participants from this danger. Individuals who agree to participate in research should be protected by legislation that prevents the loss of health insurance or other socioeconomic consequences.[30] Fuller et al[29] recommend that current practices that protect confidentiality of information in genetic research be examined for best practices and shared among researchers and IRB members to improve the process of protocol review.

Ensuring informed consent

Acting to ensure informed consent of participants donating human biological materials is an important area to be addressed given the futuristic nature of research that uses stored human biological material. Acting within the framework of the stewardship model, investigators recognize donors as the legitimate owners of donated biological material and are obligated to furnish the research participant with the information they need to direct the use of the sample donated. Two major issues that must be addressed to ensure informed consent are: (1) whether researchers can use stored tissue and biological samples for new research if they initially were obtained without specific consent and (2) how researchers can best obtain informed consent for studies that will be conducted in the future but are not yet designed or approved.[2,7,31] It is generally accepted that unidentified or unlinked human biological samples and tissue can be used for research, even if consent was not expressly received when the sample was collected; however, McEwen and Reilly[7] state that the subsequent use of the donated sample should be one that could not have been anticipated at the time of collection. Research participants who are being asked to donate tissue and biological material samples for studies that will be conducted in the future should have prospective consent forms that include detailed information regarding the anticipated research use of the sample in future research.[30]

Local IRBs play a key role in determining the adequacy of informed consent, ensuring research participation is voluntary, and ensuring risks to the participant are minimized. In the United States, research that is funded or regulated by federal agencies must be reviewed by an IRB; however, this has not been the case in some countries

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such as Sweden. Nilsson and Rose[32] report that new ethical guidelines were developed in Sweden to address the increased number of requests from biotechnology companies to access the country's genetic databases. To decrease the risks to donors, Sweden proposed new guidelines that require the approval of the local ethics committee for each withdrawal from a tissue bank and an informed consent from the donor for each new use of material stored. In the United States, McEwen and Reilly[7] state that a model code of conduct for DNA banks should include the development of written agreements that describe the rights and obligations of the donor and the researchers accessing the bank. Guidelines issued by the American College of Medical Genetics state that donors should have the option to have their samples withdrawn or destroyed at any time.[33]

Using human biological samples for the benefit of the donor

The increased value of human biological materials for the development of marketable products such as pharmaceutics, artificial skin, material for gene sequencing, development of cell lines, and gene patents increases the risk that a donor will be exploited for commercial gain or that violations in religious or cultural values will occur.[33] The stewardship model places accountability with the investigator for the responsible use of human biological materials entrusted by the donor and requires that any change that occurs to the material donated serves the donor's intent and preserves the donor's human dignity.

Commercialization must be consistent with the intent and voluntary participation of the donor. Accompanying informed consents with detailed information sheets that specify if commercial biomedical companies will have access to donated and stored biological material and informing donors in advance if they will gain from commercial use are two suggestions to achieve commercialization consistent with the donor's intent.[34] When researchers or private commercial biomedical firms, in order to meet their needs for commercial development, specifically identify and select a family, group, or community for the genetic characteristics of their tissues, the responsibility of the investigators and developers is particularly strong. In these cases, the researcher or commercial firm should be held accountable and committed to the interests of the donors.[34] When this commitment to family interests is missing, critical ethical conflicts arise such as those that occurred with the families whose children died from Canavan disease.

IMPLICATIONS FOR NURSING

Advocacy and protection of human rights are fundamental roles of the nurse. The ethical knowledge that nurses use in their discipline to assist them in decision making regarding the appropriate course of action in their roles of advocate and protector of human rights evolves through experience and personal reflection. Carper[35] identified this ethical knowledge as a fundamental pattern of knowing in nursing. The ethical decisions and actions that nurses take to protect human participants in research and minimize research risks are significant aspects of the profession's commitment to protect the health and safety of the individual and society at large. Research involving human biological materials presents a new

context within which the profession's ethical obligation to the individual, family, and community must be considered.

Whether a nurse acts or fails to act as an advocate in the protection of human participants in research has far-reaching implications. In the instance of the Tuskegee syphilis study, the nurse, Eunice Rivers, was instrumental in recruiting and keeping African American males enrolled as study participants even though she was aware that the men enrolled in the study were not receiving the syphilis treatments they were promised.[36] Recently, an investigational drug trial of a melanoma vaccine at the University of Oklahoma College of Medicine was halted by federal investigators after the nurse coordinating the study, Cherlynn Mathias, reported that the principal investigator had begun allowing patients to give self-injections at their homes, a breach in the study protocol. She complained to federal authorities when university officials refused to act on her complaints. As a result of the federal investigation, all research was halted at the university until the federal investigation was completed.[5] These cases serve as powerful examples of the effect nurses can have on the protection of human subjects in research.

In the context of genetics, nurses have been concerned primarily with the social, psychological, and ethical issues involved in genetic testing.[37] An exception is Bragadóttir,[38] who addressed the rights of children as human subjects when collecting genetic materials for a national database. The ethical issues related to the use of human biological materials in research and the nurse's role in minimizing risks to research participants need further discussion in the nursing literature.

The identification of ethical issues in the collection, storage, and use of human biological materials in research and the actions that assist in avoiding or resolving ethical conflicts need further development. The stewardship model presented in this article is a deductive model that can be used as a framework to guide actions to minimize risks to research participants donating human biological material. Inductive inquiry is still needed to further explore and validate components of the model. For example, conducting interviews with individuals, families, and groups is one method to explore personal meanings related to donation of biological materials. What practices can researchers implement that preserve the intent of the donor of human biological material, and at the same time change what is stewarded to increase scientific knowledge and benefit the community as a whole? Inquiry that answers similar questions will validate and expand the stewardship model components.

SUMMARY

The identification of social, psychological, and economic risks to persons who have donated biological materials may be easily overestimated or underestimated. The identification of possible harms to a participant in research does not mean these harms are certain or even likely.[2] However, investigators and reviewers of research protocols using human biological materials must be knowledgeable concerning areas of research risk to human participants that have emerged as a result of the advances in genetic research. Failure by the scientific community to respect the values and concerns of society could lead to an erosion of public trust and

confidence and a demand to stop all research involving human biological materials, similar to past protests organized to ban animal research.[15,18,39] Using the stewardship model developed in this article within the context of research with human biological materials directs investigators to make research design and protocol decisions that serve the interests of donors and their communities while preserving the donor and the community's shared values, traditions, and culture. Nurses are in an ideal position to advocate and ensure that the interests of research participants are served.

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