

## Genetic Biobanking for Research Position Statement International Society of Nurses in Genetics

### **Overview**

Genetic biobanking for research is the storage of donated human biospecimens or clinical information, e.g., blood, tissue, or genetic data, that will be used in future genomic and genetic research (Hewitt, 2011). Analysis of genetic data combined with corresponding clinical data offers the potential for increased knowledge of disease processes that affect human health. Genetic biobanks promote efficiency through multidisciplinary and multi-institutional efforts in the collection, management, and distribution of genomic and genetic data for future research use (Frazier, Sparks, Sanner, & Henderson, 2008). Nurses across various settings will encounter individuals faced with decisions regarding genetic biobanking (Hewitt, 2011). Genetic biobanks are also a rich data source for nurse researchers. Therefore, nurses need to understand the benefits, risks, and ethical issues associated with the application of this technology in order to effectively educate, advocate for, and support individuals and families.

The benefits of genetic biobanking are primarily associated with the potential to gain knowledge through future genomic and genetic research on disorders that require large numbers of biospecimens and corresponding clinical data. Given the time between biospecimen banking and the analysis of aggregate data, future findings are more likely to benefit the greater society and future clinical populations than specific participants who contributed data. Ethical issues associated with genetic biobanking rest primarily with issues of confidentiality, informed consent as well as disclosure of future results and data ownership (Holtzclaw-Williams, Schepp, McGrath, & Mitchell, 2010; Holtzclaw-Williams, Nemeth, Sanner, & Frazier, 2013). This position statement focuses on the ethical issues arising from genetic biobanking for use in future genomic and genetic research and the responsibilities of nurses in the application of this technology.

### **Ethical Issues**

#### **Confidentiality Concerns**

The vast amount of potentially identifiable genomic and genetic information poses challenges to maintaining participant confidentiality (Henderson, 2011). Consequently, breach of participants' confidentiality is one of the major potential harms associated with genetic biobanking research (Budimir et al., 2011). For this reason, guidelines to promote the ethical conduct of research involving genetic biobanking for research and to protect the confidentiality of participants should be in place (Hewitt, 2011). However, there is substantial variability in policies worldwide, the interpretation of existing regulations, and the implementation of guidelines regarding participant confidentiality (Zika et al., 2010). The absence of standard policies may lead to an influx of genetic biobanking research activities in countries setting the lowest standards on participant confidentiality protection (Zika et al., 2010).

#### **Informed Consent**

An issue to consider regarding participant informed consent for genetic biobanking research involves obtaining voluntary informed consent to participate in research (Henderson, 2011). Broad data sharing for use in genomic and genetic research made possible by genetic biobanks challenges the ability to provide informed consent. For example, potential participants may be asked to consent to make their stored biospecimens or genetic data available for future studies for which the aims are not yet known. Attempting to describe future research may confuse rather than assure the participant (National Bioethics Advisory Commission, 1999), and information gained may be misinterpreted or provoke distress in the participant (Budimir et al.,

2011). However, the best protection of participants' interests remains an ethically sound informed consent (Henderson, 2011). The informed consent process should include providing potential participant information regarding the scope of anticipated genetic research activities such as future data sharing, potential benefits and risks, whether future results will be disclosed, confidentiality protections, options for withdrawal of consent, and data ownership (National Institute of Health, 2013). Additionally, potential participants need to be aware that withdrawal of informed consent from future participation may be challenging due to the nature of broad data sharing of de-identified datasets. Moreover, potential participants are required to be informed that if the biobank closes, the data will likely be transferred to other entities (Zawaha, Borry, & Howard, 2011).

### **Disclosure of Future Results and Data Ownership**

An additional consideration for the use of genetic biobanking data includes informing participants about genetic findings. In basic research that involves the collection of physiological data for which the clinical/health implications of findings for individual participants remain uncertain, there is a debate regarding the feasibility of returning research results to these participants (Ravitsky & Wilfond, 2006). Even if genomic health information derived from such results proves to be clinically useful to participants, the procedures used to de-identify shared biobank data to maintain participant privacy and data confidentiality may make it impossible to provide participants such information.

The debate regarding biobanked data ownership remains largely unresolved. Some argue that completely de-identified data is ownerless; however, others believe participant donors should maintain ownership or participant donors should share ownership with the research team and the institution (Budimir et al., 2011). Questions regarding ownership of the biological data make genetic biobanking a challenging new domain of research (Budimir et al., 2011).

### **Recommendations for Nursing**

It is the position of the International Society of Nurses in Genetics that the professional nurse should:

- be knowledgeable about genetic biobanking research practices and related ethical issues;
- advocate for the protection of human subjects in genetic biobanking for use in genomic and genetic research;
- ascertain that potential participants provide informed and voluntary consent for use of their biospecimen and clinical data;
- contribute to the development of genetic biobanking procedures and protocols for the safe collection, management, storage, and dissemination of genomic, genetic, and corresponding clinical data, including advocacy in processes to achieve consensus regarding biobanking guidelines and regulations; and
- educate the public regarding the purposes, benefits, and risks associated with genetic biobanking research.

In addition to the above recommendations, nurse educators are advised to include information about genetic biobanking research in the research curriculum. Nurses who are prepared at an advanced level are encouraged to be involved in legislation and policy formation regarding genetic biobanking for use in future genomic and genetic research and consider generating research through use of genetic biobank data to advance the understanding of diseases and biobehavioral human responses to these conditions.

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Written by the following International Society of Nurses in Genetics members:

Sandra Daack-Hirsch, PhD, RN, College of Nursing, The University of Iowa

Andrew Dwyer, RN, FNP University of Lausanne and the Centre Hospitalier Universitaire Vaudois (CHUV), Lausanne Switzerland

Pamela Holtzclaw-Williams, JD, PhD, RN, College of Nursing, University of Arkansas for Medical Sciences

Jennifer Sanner, PhD, RN, School of Nursing, The University of Texas Health Science Center at Houston

Audrey Tluczek, PhD, RN, School of Nursing, University of Wisconsin-Madison

Marie Twal, DrPH, CPNP, Indiana University of Pennsylvania

John Twomey, PhD, PNP

Catherine Tymkow, ND/DNP, APRN, WHNP-BC, College of Health & Human Services, Governors State University

Erica Yu, PhD, RN, ANP, The University of Texas Health Science Center at Houston