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## Abstract

Nurses are a pivotal component of the translational research movement and apply scientific discoveries to the healthcare and clinical practice fields. Biobanking is also an important factor in furthering translational research by providing biospecimens and related clinical data to the research community. The effectiveness of any biobanking effort necessitates the enrollment of large numbers of diverse participants, which signifies a need for the nursing profession to secure the knowledge necessary to impact biobanking practices and to promote participant advocacy. In addition, biobanks provide the volume, variety, veracity, and velocity of data that can address the challenges of nursing research. Nurse scientists, research nurse coordinators and clinical research and practice nurses must be informed about the various benefits and risks associated with biobanking in addition to ethical issues surrounding informed consent, participant privacy, and the release of research results. Ultimately, nurses need to possess competencies to facilitate biobanking practices both at the research bench and at the point of care.

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## Keywords

Nursing practice • Biobanking • Informed consent • Nursing competencies  
• Ethics • Genetics and genomics

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## 12.1 Introduction

Nurses are at the forefront of the translational research movement, promoting the transfer of basic science discoveries to healthcare applications and clinical practice [1]. Biobanking has also played an important role in furthering translational research by providing large numbers of readily accessible biospecimens and related clinical data to the research community. Furthermore, biobanking has revolutionized the methods in which data are collected and obtained as well as added a new dimension to nurse-research participant interactions. Ultimately, nurse scientists, research nurse coordinators and clinical research and practice nurses must be knowledgeable about the various benefits, risks, and ethical issues associated with biobanking.

Researchers, including nurse scientists and nurses involved in various aspects of research, need to be aware of the potential benefits and risks associated with biobanking and need to be involved in protecting the rights of the participants. The benefits of biobanking include access to biospecimens and related clinical data for use in research studies, at times circumventing the necessity for an individual research project to recruit their own research participants and use larger amounts of research funding. Biobanks may also provide genomic data (e.g., whole exome sequencing, single nucleotide polymorphism (SNP) analysis), which may be very useful to researchers conducting genetic studies and genome-wide association studies. Furthermore, biobanks promote and facilitate broad avenues of research, potentially benefiting the health of society. In addition, the inclusion of nursing-relevant data may be geared towards answering nursing research questions [2].

The ethical issues associated with biobanks include but are not limited to protecting the privacy of the participant and the potential for discrimination against the biobank participant. Successful biobanks call for adequate human subjects' protection and data privacy protection necessitating the education of professionals, including the nursing profession [2]. Overall, biobanking produces many benefits associated

with its incorporation into translational research; however, risks, primarily to the participants, are also involved in biobanking and should be considered by researchers, including nurse scientists, in developing and utilizing biobanking practices.

Three essential ethical considerations of biobanking or research involving human subjects are protecting the identity of the participant and data privacy, ensuring that the research participant has provided informed consent, and the potential disclosure of results or incidental findings [3]. Components to the informed consent process for potential biobank participation necessitates language in the informed consent which addresses identity protection and data privacy measures, allows for the sharing of the contributed data in future unknown studies and discloses the potential for discovery of future results or incidental findings, all of which may be challenging to explain to potential participants. Nurse scientists, research nurse coordinators, and clinical research and practice nurses all play important roles in shaping and exercising biobank practices, especially principles involving advocating for and protecting the rights of the research participants, including the informed consent process. Nurses should address these ethical considerations of biobanking by educating themselves, interdisciplinary team members, participants, family members, and the public about biobanking; by serving as participant, family, and public healthcare advocates; and by engaging in healthcare policy that influences biobanking practices [2].

As an integral component of the translational research movement, the genomics revolution has greatly impacted current research and influenced biobanking practices. Because a biobank may serve as a virtual or concrete repository for the storage of large numbers of human biospecimens and related clinical data, researchers conducting genetic research, which often requires a large collection of biospecimens, may use a biobank to gain access to large amounts of data. As the fields of genetics and genomics have grown, the nursing discipline recognizes the importance of incorporating the practices and competencies necessary to conduct cutting edge genetic research and incorporate genetic knowledge into

clinical practices in the genomic era, including biobanking practices. Specifically, these competencies include professional responsibilities such as knowledge, skills, and values and professional practice considerations such as nursing assessments, identification, referral activities, and provision of education, care, and support [4]. Biobanking and genetics and genomics are often intertwined practices; therefore, these competencies also apply to nursing professionals involved in biobanking. While not meant to be a comprehensive review, in this chapter, we will discuss various nursing roles influencing biobanking practices and research; outline competency standards for nurses, especially in the area of genetics and genomics and biobanking; and highlight pertinent ethical considerations for nursing research and practice involved in biobanking.

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## 12.2 Nursing Roles Impacting Biobanking

With the advent of translational research, patients are increasingly solicited to as potential biobank participants to contribute personal data to supply biobanks [5]. The effectiveness of any biobanking effort necessitates the enrollment of large numbers of diverse participants representing populations of interest [2, 6]. This request of potential participants signifies a need for the nursing profession to respond by securing the knowledge necessary to impact biobanking practices and to promote participant advocacy. The characteristic ethical perspectives the nursing discipline brings to healthcare and research practices are valuable because biobanking practices should be implemented with the protection and benefit of the biobanking participants in mind. Influence from the nursing discipline is seen as an integral component of biobanking practices highlighting the discipline's position in promoting participant trust, conducting nursing research, and improving clinical practice [7]. Furthermore, including a nursing component in biobanking encourages biobank data contributions that are meaningful to nursing-relevant research ques-

tions as well as questions that specifically impact the nursing discipline and clinical practice [2].

Genetic and genomic science discoveries, repeatedly generated through the use of biobanked data, are redefining our understanding of disease and human health. Although the full potential of genomic healthcare and biobanking usability has yet to be realized, it is critical for nurses to understand and develop competencies in genetics and genomics to build a foundation for the application of nursing practices in biobanking. The application of genomic and genetic discoveries in healthcare continues to improve our understanding of disease prevention, diagnosis, and treatment, and biobanks function as a catalyst for these discoveries by supplying large numbers of human biospecimens and related data to researchers conducting genomic and genetic research, including nurse scientists [8]. Biobanks provide the volume, variety, veracity, and velocity of data that can address the challenges of nursing research such as the need for large sample sizes. Therefore, researchers and healthcare providers alike, including nurses, need to understand the benefits, risks, and ethical issues surrounding biobanking to effectively impact biobanking practices. Nurse scientists, research nurse coordinators, and clinical research and practice nurses all possess unique attributes that can contribute to and influence biobanking practices.

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## 12.3 Nurse Scientists

Similar to scientists in other disciplines, nurse scientists focus on advancing scientific discoveries; therefore, their professional roles may also include generating new scientific knowledge using biospecimens, genomic data and clinical data obtained from biobanks. The National Institutes of Health (NIH)-supported Clinical and Translational Science Award (CTSA) program was launched in 2006, and many centers include a core biobank component as an important piece of the translational research process [9]. Nurse scientists continue to be actively involved in the

development and advancement of CTSA programs, including biobank components, requiring nurse scientists to emphasize collaboration and participation within biobanks and across disciplines within CTSA centers [1].

Nurse scientists may also use biospecimens and data retrieved from biobanks in their own studies; therefore, they need to be involved in the development of biobanking resources such as the collection of nursing-relevant data including bio-behavioral, health-related quality of life, cost of care and patient outcome data [1, 2]. In addition, nurses who are prepared at advanced educational levels should consider being actively involved in legislation and policy formation regarding biobanking practices. This governance includes biobanking use for genomic and genetic research, as well as generating research using biobanking data to advance the understanding of disease processes and human responses, symptom advancement, and self-management of these conditions [3].

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## 12.4 Research Nurse Coordinators

Research nurse coordinators may engage in biobanking activities such as providing research staff oversight in participant recruitment; supervising data collection measures (including working with laboratory personnel to implement standardized biospecimen collection, handling, processing and storage protocols); direct data recording and management (including working with informatics personnel to standardized data processing and security protocols); ensuring compliance with institutional regulatory requirements and reporting; and preserving the integrity of biobanking protocols. Therefore, research nurse coordinators must understand, implement and follow ethical guidelines specified by the governing Institutional Review Board (IRB) and Committee for the Protection of Human Subjects (CPHS). For example, an important aspect of following established human subject protection guidelines may include research nurse coordinator involvement in the development of the informed consent for a biobank to ensure that biobank participants' rights are protected.

## 12.5 Clinical Research and Practice Nurses

With the increase in the use of biobanks in trials, it is critical for clinical research nurses to stay informed of the emerging ethical, clinical, and regulatory issues involving human subjects, including biobank participants. Clinical research nurses, frequently under the direction of nurse scientists or research nurse coordinators, often focus on fundamental biobanking activities to promote research endeavors, including obtaining participant informed consent and biospecimen and clinical data collection [10]. Therefore, it is imperative that clinical research nurses involved in biobanking have a comprehensive understanding of biobanking practices, including the ethical considerations surrounding the informed consent process and data integrity measures.

Potential participants are approached to partake in a biobank by a recruiter who may be a clinical research nurse. The initial informed consent process involves a purposeful and continuing exchange of information between the members of the research team and the potential participant throughout the research experience, and the clinical research nurse may be the representative of the research team who interacts with the participant to obtain the informed consent. While the clinical research nurse typically obtains the actual informed consent, the clinical practice nurse may perform multiple functions at the point of contact with the research participant, including reinforcing participant understanding of the informed consent process. Therefore, the clinical practice nurse may function as an extension of the biobanking research team [7].

Along with clinical research nurses, clinical practice nurses are often involved with data collection at the point of care; therefore, they often directly influence the quality of biospecimen and clinical data obtained for biobanking, and competent nurses ensure the validity of the collected biospecimens and phenotypic data. Once the patient has acquiesced to becoming a participant of the biobank, clinical research and practice nurses must understand and execute standardized techniques essential for the proper collection, handling, processing, and storage of biospecimens

and related clinical data. While nurse scientists and research nurse coordinators often establish and supervise standardized data protocols for data received by the biobank, clinical research nurses, and when appropriate clinical practice nurses, should be knowledgeable in these processes to facilitate the entry of intact data into the biobanking system. In acquiring data to deposit into biobanks, clinical research and practice nurses have an obligation to obtain quality data and related documentation.

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## **12.6 Genetic and Genomic Nurse Competency Standards Impacting Biobanking Practices**

Since the completion of the Human Genome Project in 2003, the importance of understanding and applying genetic and genomic information in nursing practice and nursing research has been recognized [11, 12]. As more patients are recruited into genetics and genomics studies that may involve biobanks, nurses will have increased opportunities to interact and be involved in the various aspects of biobanking operations and practices. To promote the understanding of genetics and genomics in the nursing field, the American Nurses Association (ANA) with the National Human Genome Research Institute (NHGRI), the National Cancer Institute, and the Office of Rare Diseases of the National Institute of Health organized a panel of nursing experts to establish a consensus on essential genetics and genomic competencies for all registered nurses [11]. After reviewing the available competencies, guidelines, and recommendations, “The Essential Nursing Competencies and Curricula Guidelines, 1st Edition” was published and endorsed by major professional nursing organizations including the National Coalition for Health Professional Educators in Genetics (NCHPEG) [11]. This guideline identified and implemented essential competencies to guide nurses in making the connection between bench genetic and genomic knowledge and point of care [4, 11].

The two domains of essential competencies identified for nurses are professional responsibili-

ties and practice [4]. Professional responsibilities include the professional role of nursing practice as specified in the nursing scope and standards of practice [4]. Nurses at all levels, including nurse scientists, research nurse coordinators and clinical research and practice nurses, are required to be knowledgeable and competent in utilizing genetic and genomic knowledge and skills, and the first step is to recognize one’s own attitude and values related to genetic and genomic discoveries [4]. In addition, essentials in the professional practice domain address nursing competencies such as nursing assessment, patient identification, referral activities, and patient support [13]. In the assessment areas, understanding the importance of genetics and genomics related to health prevention, screening, diagnosis, prognostics, and treatment are considered important competencies [11]. With the essential knowledge in professional responsibilities and practice, nurses are in a pivotal position to promote trustworthy biobanking practices in the genetic and genomic era today and in the future. The Educational Resources on Genetic Biobank Applications list provides educational resources related to genetics and genomics and biobanking, including topics of specific interest to the nursing profession.

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## **12.7 Ethical Genetic and Genomic Considerations for Nursing Research and Practice Involving Biobanking**

During participant recruitment for biobanks, nurses, frequently clinical research nurses, provide relevant information to the potential participant, obtain informed consent, and answer questions regarding biobanking practices. For genetic biobanks, the large-scale collection of biological samples and related clinical data raises serious concerns regarding the privacy and confidentiality of biobank research participants. To address these concerns, the Ethical, Legal, and Social Implications (ELSI) program was founded by the NHGRI in 1990 as an essential part of the Human Genome project [14]. Notably, the ELSI program focuses on ethical issues surrounding the design and conduct of genetic research,

including informed consent [15]. The paramount issues that are highlighted by the ELSI program associated with the informed consent process include the scope of the informed consent, informed consent content, protection of participant privacy and confidentiality, return of research results or incidental findings, termination of participation, custodianship and intellectual property rights, and access to and sharing of genotypic and phenotypic data [16]. Even though the purpose of ELSI was to proactively address the issues from genetic and genomic studies, biobanks practices are often included in the discussion, specifically related to broad prospective consent and return of significant or incidental results [17]. These ethical dilemmas addressed by the ELSI program pose novel challenges for nurse scientists, research nurses, and clinical practice nurses conducting genomic and genetic biobanking research [18].

Although the biospecimens stored in a majority of biobanks are de-identified to protect participant privacy, genetics and genomics data contain unique identifiers for each person. In 2008, the Genetic Information Discrimination Act (GINA) was signed into federal law, which protects against employer and health insurance discrimination due to personal genetic information [19]. Nurses involved with genetic biobanks need to become familiar with the scope and limitations of GINA to further their awareness of

governances protecting biobank participants. GINA may potentially lessen the participant's fear of potential discrimination based on sharing their genetic information and increase their willingness to participate and donate biospecimens into biobanks for future research.

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## 12.8 Conclusion

Researchers using biobanking resources are becoming increasingly widespread as scientists, including nurse scientists, recognize the need for large quantities of quality biospecimens and data. Consequently, the nursing profession has continued to broaden and evolve as biobanking expands. The perspectives the nursing profession brings to biobanking practices ensures that biobanks are designed with the protection and benefit of potential biobank participants and the contribution of pertinent nursing-relevant data meaningful to answering questions posed by nurse scientists. As genetic and genomic influences on healthcare multiply, the nursing profession is required to maintain professional competencies and address genetics and genomics and related ethical issues including those surrounding biobanking. The role of the nursing profession will become increasingly important as the breadth and scope of biobanking practices spread.

### Educational Resources on Genetic Biobank Applications

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The *Journal of Nursing Scholarship* Genetic Nursing Series Covers Important Perspectives to Prepare Nurses for the Translation of Genomics into Practice <http://www.genome.gov/27552093>

A Video Webinar of this Series is Available at <http://www.genome.gov/27552312>

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A Series of Genetic/Genomic Articles by the National Human Genome Research Institute and National Cancer Institute for Nursing Educators <http://www.genome.gov/27543639>

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Genetic Biobanking for Research Position Statement by the International Society of Nurses in Genetics (ISONG) [http://www.isong.org/documents/BiobankingPositionStatementFINAL\\_February2014.pdf](http://www.isong.org/documents/BiobankingPositionStatementFINAL_February2014.pdf)

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2012 Best Practices for the Collection, Storage, Retrieval and Distribution of Biological Materials for Research from the International Society for Biological & Environmental Repositories <https://isber.site-ym.com/?page=BPR>

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The Organization for Economic Co-operation & Development Guidelines for Human Biobanks and Genetic Research Database <http://www.oecd.org/health/biotech/guidelinesforhumanbiobanksandgeneticresearchdatabaseshbgrds.htm>

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National Human Genome Research Institute National Institutes of Health Informed Consent Form Examples & Model Consent Language <http://www.genome.gov/27526660>

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Genetic Resources of Particular Interest for Nurses by Cincinnati Children's Hospital <http://www.cincinnatichildrens.org/education/clinical/nursing/genetics/default/>

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