Overcoming Challenges in Providing Biospecimens for Commercial Use
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Background: As the market for biobanking services has expanded rapidly to meet the needs of the pharmaceutical and the personalized-medicine industries, non-profit institutions such as hospitals offer a potential, unlimited supply of biospecimens. However, the expense of biobanking operations and ethical concerns regarding the transfer of sample ownership, continue to challenge these non-profit organizations. Many organizations cannot justify the expense of a biobanking operation to their stakeholders, and are troubled by the ethical concerns arising from sample ownership and patients’ concerns in allowing donated samples to be used by companies that could financially gain from the samples. Yet, the potential contribution to society in the development of cures for diseases, more effective treatments, and new diagnostic and screening tests is a valid consideration.

Research Question and Findings: How might these challenges be overcome? The cost of biobanking can be mitigated through strategic planning, stakeholder buy-in, and collaboration. Non-profit biobanks that provide samples for commercial use have the opportunity to acquire additional revenue for growth and long-term sustainability. In order to do this, these types of biobanks also need to address concerns regarding sample ownership and the public perception. There have only been a few state cases in which the issue of sample ownership has been addressed and, in all these cases, donors did not retain property interest in their donated samples. Courts have emphasized the importance in having clear language regarding ownership and intellectual property rights between the institution providing the specimens and the researcher receiving these specimens, as well as clear language within the informed consent document. The National Cancer Institute, the Office for Human Research Protections, and the Food and Drug Administration have provided guidance prohibiting exculpatory language and provide examples of acceptable language for the informed consent. It is also important that biobanks determine the appropriate amount of information to provide volunteers within the informed consent document so that a volunteer is not overwhelmed with unnecessary information.

Conclusions: In regard to patients who are reluctant to provide specimens to biobanks that allow commercial companies to access their inventory, literature suggests that this concern can be minimized with education on the importance of private companies continuing their work to produce medical benefits for individuals and for society as a whole. To maintain trust of patients, it is important to have clear, transparent language in informed consent documents to ensure patients understand their rights in commercial use of their biospecimens.