All for one and one for all

The development of large-scale centralized biobanks raises the stakes in a familiar conversation on ethics in medical research and poses unique challenges to lawmakers that will require informed discussions between scientists and the public.

Biobanks collect, store and process human biological specimens and maintain clinical data associated with these samples. The term biobank encompasses both small collections in laboratories or hospitals and large-scale repositories. New high-throughput technologies drive the need for larger biobanks with state-of-the-art capabilities (see p.173).

Streamlined management of tissues and information by centralized biobanks can benefit society by providing scientists access to samples at a scale that revolutionizes medical research. Ethical issues that apply to biobanking overlap extensively with those associated with medical research; these include questions about sample ownership, informed consent and anonymity. Additional ethical complications specific to centralized biobanks have also surfaced. As the ultimate success of biobanks depends on the participation of individuals, scientists need to engage the public in a conversation about biobanking to establish guidelines that protect both individual and public interests.

Questions concerning ownership of biological samples are complex. From a legal perspective, ownership invokes property rights, and it remains unclear whether individuals 'own' their intact bodies, let alone the pieces of them that are excised or extracted. Individuals are protected against involuntary excision of their tissues, but, with certain exceptions, they are not permitted to sell their tissues or organs. Individual control over medical samples lies in the gray area between the two extremes of individual and communal ownership. In some situations, samples are biobanked unbeknown to the individual. While questions about ownership remain unresolved, most scientists and clinicians obtain informed consent to circumvent the issue.

Informed consent involves three components: information, comprehension and free will. Individuals vary in their ability to comprehend information relevant to their consent, which minimally includes the nature of the procedure and the implications of their participation in a research study. Thus, providing necessary information and subsequently establishing comprehension are both essential aspects of obtaining consent. The final component of informed consent is free will.

Informed consent is confounded by the formation of large biobanks that provide samples for a myriad of distinct studies. Ethicists debate whether informed consent can be given broadly to accommodate multiple aims or whether specific consent for each additional study is necessary. In practice, it is more efficient to use banked samples and data for multiple studies. Thus, broad consent is desirable. But, by definition, the more general consent is, the less informed it is. Large-scale biobanks, such as UK Biobank, favor the establishment of broad consent, thereby eliminating the arduous task of obtaining reconsent.

Sample anonymization—another alternative to reconsent—is an acceptable solution that preserves individual rights to privacy while maintaining valuable samples for research. Anonymization, however, prevents the powerful combination of life-long medical information with genetic and biological data essential for determining the causes of and cures for elusive diseases; thus, anonymization diminishes the potential public benefit.

Centralized biobanks raise new questions concerning distribution. Practical and ethical questions abound, including: should access be granted to both public and private entities; who is responsible for the long-term protection and management of data; who arbitrates debates over access; and is it acceptable for individuals or institutions to profit financially from their access?

Similar to ethical questions surrounding medical research, conflicts between public and individual interests underlie ethical challenges in biobanking. High-throughput evaluation of human samples promises to generate disease-specific knowledge that cannot be obtained by other means. This knowledge should lead to more effective treatment of individuals and a healthier population. Thus, the potential public benefit if individuals participate in biobanking is enormous.

It is also important that society protect the rights of individuals, so limiting access to biobanks is crucial. Data acquired from samples in biobanks should not be plundered for insurance, employment or any other form of discrimination. Restricting access should prevent predators from targeting vulnerable populations for commercial gain. Finally, establishing legal guidelines defining accessibility would promote transparency. Protection of biobanks is essential because the risk to individuals for the misuse of data is high.

It is necessary for scientists to engage the public in a conversation on biobanks. The onus to meet the ethical and practical challenges presented by the rise of biobanking is on scientists. It is also incumbent upon lawmakers to provide a legal framework that protects public and individual interests. If fear of negative repercussions or unethical use of personal information causes individuals to opt out on a scale that undermines public health initiatives, everyone loses.