

Commentary

Broad consent and biorepositories for molecular epidemiology and genomics research

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Biorepositories containing blood, DNA, tissue or tumor samples are likely to continue to spur progress in biomedical science in such diverse areas as childhood health concerns (e.g., birth defects, attention deficit hyperactivity disorder), adult-onset chronic diseases (e.g., coronary heart disease, cancer, diabetes, and osteoporosis), stroke, dementia, Parkinson's disease, amyotrophic lateral sclerosis, and other neurological conditions, and psychiatric conditions such as major depression and post-traumatic stress disorder. In order for the promise of biorepositories to be fully realized, there is an ongoing need for attention to be given to how they are organized and to ensure that the individual rights and autonomy of research participants are adequately respected [1].

Consent procedures for participation in molecular epidemiologic or genomics research can be thought of as a continuum from highly specific consent for a particular study, to consent for research on a specific disease (for example, studies of asthma or chronic bronchitis), to broad consent for biomedical research [2]. In the context of biorepositories, broad consent means that donors give permission to use samples and data for multiple purposes of future biomedical research [3]. Concepts of broad consent for biobanking have been extensively discussed and debated in the bioethics literature. Arnason argued that "the more general the consent is, the less informed it becomes" [4]. However, others have argued that broad consent does adequately respect research participants and is consistent with informed consent for mo-

lecular epidemiologic or genomics research [1, 2]. From a scientific point of view, future research may be hindered if the informed consent is too strict, partly because many studies will not have been planned or conceptualized at the time consent is given. Research methods are also advancing rapidly. For example, at the beginning of the decade it took years to sequence the first complete human genome, but as many as 25,000 will be sequenced by the end of 2011 [5].

Part of the debate over the adequacy of broad consent may be due to a failure to adequately define concepts and terms that are at the heart of the debate. Some commentators have inexplicably used the term broad consent interchangeably with the notion of "blanket consent" which is the least specific form of consent and the most difficult to reconcile with widely accepted norms of informed consent for biomedical research. The term "blanket consent" implies that there will be no restrictions regarding the purpose of the research [2], which is rarely the case since most large-scale biorepositories are set up to facilitate general programs of research as determined by institutional values and aspirations of the biobank. A further issue is that not all commentators have considered the level of risk posed by the research. In assessing the risks and potential benefits of a proposed study, institutional review boards (IRBs) or ethics review committees consider how personal data will be safe-guarded so as to rigorously protect confidentiality and privacy and the level of risk posed by the research.

In the midst of scientific and ethical discourse about how best to obtain informed consent for large-scale molecular epidemiologic and genomics research involving the establishment and use of biorepositories, Sheehan [1] recently addressed the question, "Can broad consent be informed consent?" His analysis leads to a rejection of arguments made by others that the lack of specific information about particular uses of samples means that such consent cannot be fully autonomous or ethical. He notes that autonomous people regularly make many straightforward decisions that are analogous to the broad consent decision to participate in a biorepository [1]. A noteworthy aspect of Sheehan's analysis is that he points to the governance arrangements employed in many large-scale biorepositories or biobanks (depending upon institutional policies and governmental regulations and laws). At many institutions, when an individual gives broad consent to the use of their sample or data in future research they are giving permission for the governing body of the biorepository to decide how to use that sample or data (with IRB or ethics review committee oversight). At the time consent is obtained, research participants are provided with an account of the general program of research and an account of the general goals of research or the institutional values and aspirations of the biobank [1].

In several countries, there has been a gradual shift towards allowing biorepositories to obtain broad consent for future research using either anonymized samples or coded samples and data. This practice has been defended in the context of large-scale longitudinal studies on genomic variation. Hansson et al. [2] argued that broad consent for future research is ethical and should be recommended for biobank research provided that personal information is handled securely, that donors of biological samples have the right to withdraw their consent, and that new research studies be approved by an ethics review board. Their arguments in favor of broad consent for future research is partly based upon a low risk of potential harms from the research and having adequate measures in place for minimizing such risks [2]. Most institutions require that the reuse of biological specimens be consistent with the consent under which they were collected and that the reuse only occur through an IRB or research ethics committee-approved protocol. The movement

towards greater uniformity in laws and norms for large-scale biorepositories and biobanks, both within countries and internationally, is likely to be helpful for ethics review committees and individual researchers as they navigate current institutional and regulatory requirements and aim to provide consent forms that are lucid, concise, and adequately address standards for informed consent [3, 6, 7].

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