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Phasing Out Voluntary Donation in Clinical Trials: The Ethics of Mandating Bio-specimen Collection

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Abstract

Biomarker studies are one of the primary research vehicles for gathering necessary genotypic evidence in the search for genetic etiologies of disease. Until recently, samples used for biomarker studies were almost exclusively collected from participants donating to bio-banks or dedicated genome-wide association studies. Based on observations while serving on a research ethics board in Canada, it has become commonplace for clinical trial sponsors to mandate that participants provide tissue and other DNA samples as a condition for their participation in the trial. This viewpoint argues that imposing such a condition runs counter to the premise of voluntariness upon which bio-bank donation specifically, and biomedical research generally has historically rested. Public apprehension regarding data protection and fear of genetic discrimination can accentuate the ethical dubiousness of mandating bio-specimen collection.

Introduction

Genome medicine relies on coupling clinical and sequence data to elucidate underlying disease etiology [1]. Based on the author's experience serving on a research ethics board in an urban Canadian hospital, clinical trials that include an accompanying biomarker study are becoming an increasingly common research design. Many pharmaceutical sponsors now mandate that participants provide tissue and other DNA samples as a condition for their participation in the clinical trial. This is particularly true in oncology and rare disease [2], where the intersection between research and care is converging with the routinization of next generation sequencing (NGS) [3,4]. While the convergence of research and care fuels new discoveries and has led to major advances in treatment, research suggests the public continues to harbor concern about genetic discrimination [5]; can be distrustful of the pharmaceutical research enterprise [6]; and are not always informed of the regulations for protecting data privacy and security [7]. As a result, it is possible some patients could be denied the opportunity to participate in potentially beneficial clinical research simply because they do not consent to providing biological samples/data or prefer do so on a restricted basis [8]. This viewpoint argues that mandating bio-specimen collection does not respect the voluntariness of bio-bank donation for research purposes, and could take inappropriate advantage of participants eager to enroll in these clinical trials.

The emergence of bio-banks and bio-banking practice has sparked international initiatives to enhance responsible data handling [9-12] and facilitate bio-specimen donation in biomedical research. Alternative consent models have also developed in line with the unique nature of bio-bank research [13,14], which often requires thousands, if not millions of participants to donate biological specimens or other forms of genetic data [15]. Yet, such policies have always taken as central the voluntariness of donation. The ethical question of mandatory bio-specimen collection is, in part, a utilitarian one invoked most often in public health ethics [16].

Voluntariness vs. Public Good

One the one hand, biomarker research is an essential step in the bench-to-bedside continuum where laboratory discoveries are translated into clinical applications [17]. This translational process takes approximately 17 years [18], during which time the value of biomarker data is compounded. That is the potential clinical utility of biomarker data increases with each additional sample and strengthens association(s) between specific areas of the genome and disease. The more (quality) data points from participants, the stronger the genotype-phenotype associations. In turn, new opportunities for drug discovery and other scientific investigations built on these associations are forged. Both a scientific and utilitarian defense can be made to support the expansion of biomarker research considering the collaborative nature of genomics [19,20] and the necessary volume of sequence data needed [21].

On the other hand, empirical evidence suggests patients are reluctant to provide biological samples and genomic data for reasons that include, but are not limited to data privacy, security and genetic discrimination. Where clinical trial sponsors mandate bio-specimen collection, participants must therefore accept uncertain informational risks in order to take part in the trial itself [22]. Participants often accept informational risks as part of routine clinical care, but their participation in research imposes different ethical and legal obligations. Participants should provide consent separately to bio-bank donation so as to preserve the voluntariness that has until recently been the currency of ethical bio-banking practice.

The gift-giving rhetoric of donation is reflective of the altruistic relationship between donors and bio-banks. Voluntariness and altruism are no doubt different, however. Whereas altruism involves prioritizing the needs of others of self-interests, voluntariness refers to a decision to prioritize needs as one deems fit and appeals to rights of self-determination to act either in the interests of oneself or others. Some have argued the concept of altruism in blood donation, for example, does not cohere with the values espoused by public

healthcare systems where investments in health research are borne collectively [23]. Others contend participation in research enhances solidarity and license to benefit from the fruits of scientific research [24]. Despite this, no country (with or without a public healthcare system) mandates patients to contribute bio-specimens for research purposes. Why then, should pharmaceutical-sponsored research mandate it?

Certainly biomarker research can complement clinical trial procedures with minimal additional risks to participants. Left over blood and biopsy tissue, for instance, could be saved for future research purposes rather than be discarded. The amount of blood already required as part of the trial protocol could be increased at the time of withdrawal without posing any major additional risks to the participant. While these procedures are not risky per se, they should remain optional for participants and separate from those conducted specifically as part of the clinical trial. That such procedures be mandated of clinical trial participants is an affront to the altruistic rationale for bio-specimen donation discussed earlier. Furthermore, mandatory collection could be taking inappropriate advantage of some participants' desperation for access to experimental therapies only available through clinical trials. While it is true that many participants-especially those in the rare disease community [25,26]-feel a personal responsibility to contribute their samples to research to help find cures, this is no justification for a blanket norm.

Conclusion

This viewpoint argues against making clinical trial participation contingent on mandatory bio-specimen collection. Such a practice is ignorant to the concerns that many prospective research participants feel in relation to data privacy, security and genetic discrimination, to name a few and can co-opt patients eager to access experimental therapies to accept uncertain informational risk. Based on the author's experiences, this trend is opportunistic at best and places unfair conditions on research participation that scientists depend on to drive clinical innovation.

Conflicts of Interest

Author declares no conflicts of interest. The ideas presented in this article are solely his own, and do not represent the views of his affiliate institutions.

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