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The Kindness of Strangers: The Donative Contract Between Subjects and Researchers and the Non-Obligation to Return Individual Results of Genetic Research

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Open Peer Commentaries

The Kindness of Strangers: The Donative Contract Between Subjects and Researchers and the Non-Obligation to Return Individual Results of Genetic Research

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Bioethics increasingly relies on empirical research in order to resolve ethical issues. Bioethics has also, of late, begun reimagining the researcher–subject relationship to include new positive duties to subjects, such as providing ancillary care and offering to return research results. These trends have converged in the form of a growing stream of empirical studies of subjects’ preferences about being offered research results. The latest of these is the qualitative study by Murphy et al. (2008) surveying respondents about a proposed longitudinal study of genes, environment and health, in which the United States government hopes to enroll a cohort of 500,000, primarily through door-to-door recruitment (National Human Genome Research Institute [NHGRI] 2004). The study concludes, with most, that a majority of respondents would want to be offered individual genetic results.

The question at the intersection of these trends is how we should factor this preference into research design. Though we rightly see in empirical work hope for “[b]etter informed and more sophisticated debate, which acknowledges the contribution of social science research rather than accepting uncritically the legitimacy of bioethics pronouncements” (Dixon-Woods et al. 2006, 209), we should avoid a countervailing danger of moving too quickly from empirical data to normative conclusions (Miller 2002). Some see a strong normative role for subjects’ preferences; evidence that subjects *want* results, they say, buttresses, or even entails, the conclusion that researchers have a *duty*, based on the principle of respect for persons, to offer them (Shalowitz and Miller 2005). Others argue for a minimal role: though they acknowledge that subjects may want them, they paternalistically conclude that most individual results should not be

offered (Ossorio 2006; Parker 2006). I propose that considerations of autonomy and altruism dictate a role for preferences that lies between these extremes.

Respect for persons minimally requires refraining from treating others as mere means to our ends and from obstructing their autonomous actions unless they threaten third parties. Whether this principle entails positive duties, such as enhancing another’s capacity for autonomous choice or catering to her preferences, often depends on the relationship between the parties. Despite increasing calls to view the investigator–subject relationship as fiduciary (Miller and Weijer 2006), the subject is “in essence a volunteer” (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979). While volunteer work is often risky, requiring the volunteer to entrust her well-being to those who coordinate her work, a fiduciary usually has the additional duty of acting in the beneficiary’s interests. Physicians have such a duty to their patients, but by definition research seeks not to serve the interests of participants but to create generalizable knowledge designed to benefit society and future patients. Thus, if biobank research is properly entered into, the volunteer will understand that she has donated her time and tissue to, and undertaken certain privacy risks in service of, an essentially altruistic end (better understanding and treatment of complex diseases) from which she may well never directly benefit. While subjects serve as means to this end, they are not *mere* means, because in making an informed decision to volunteer, they adopt this end as their own.

At least in this proposed biobank study, then, the researcher–subject relationship is better seen (and

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investigators are obligated to ensure that subjects see it) as governed by a sort of arms-length donative contract — an agreement under which the donor–subject agrees to make a gift to the donee–researcher, who arguably holds the gift in trust for society (especially if the research is government-funded) and does not promise anything directly in return. Because of the inherently risky nature of research, the unequal knowledge of researchers and subjects, and the long history of research abuse, the donee has duties (not ordinarily imposed by law on contracting parties) to disclose material information about the study to prospective donors, ensure understanding and voluntariness, and permit them to renege at any time.

Under this framework, it does not follow from empirical evidence that most subjects *prefer* the option of receiving results that researchers have any moral or legal *obligation* to provide them. A contract's terms need not (and in practice rarely do) reflect the ideal preferences of either party, and researchers — who are after all also persons deserving of respect — may make offers to potential research volunteers that reflect their own preferences, resource limitations, and conscientious beliefs about the wisdom of returning certain results. The acceptance of what often must be, for pragmatic reasons, a take-it-or-leave-it offer to volunteer is not invalidated, nor the ensuing research rendered unethical, because the volunteer's *gift* is not "repaid" in the form of research results or, indeed, in any form (though subjects must be told results will not be disclosed). Those who argue that "recognizing the altruism of research participants requires that investigators provide . . . research results" (Fernandez et al. 2003, 18), and that failure to do so entails "individual rights [being] forfeited for the benefit of society" (Fernandez and Weijer 2006, 45), invert the essence of altruism, which is selflessness in the service of others.

Offering results is also said to "show gratitude for participants' voluntary participation in research" and "acknowledge participants' presumptive entitlement to information about themselves" (Shalowitz and Miller 2005, 738). Although we all ought to honor volunteers, returning individual results in an ethical manner can be costly, and it would be odd (and perhaps not in keeping with subjects' *overall* preferences) if researchers had a perfect duty to honor volunteers in a way that undercut their ability to devote the maximum available resources to the research itself — the very end that should motivate the subjects to volunteer in the first place. And even if we assume that subjects own or are otherwise entitled to their genetic information, surely such property can be alienated, or such entitlements waived, through the donative contract.

A contract's terms, however, must not sink to the level of unconscionability. Researchers are not fiduciaries for subjects, but they do not have lesser obligations to subjects than they do to third parties, and we all have moral (if not legal) duties to rescue or warn others, especially when we are uniquely positioned to do so, with minimal risk to ourselves. Agreements that purport to contract around this duty

— such as those providing that researchers will not return results indicating that a subject might have a serious but treatable or preventable disease — are presumptively unconscionable. It is worth noting that even here, where researchers might be thought to have the strongest obligation to honor preferences about returning results, it is not clear that the *subject's* preferences alone determine whether the researcher must disclose. The familial nature of genetic information arguably extends a researcher's duty to warn to the subject's relatives, whose preferences may have independent weight.

Ironically, those who draw the strongest connection between subjects' preferences and researchers' duties — by claiming that the former entail the latter — render empirical data about preferences of minimal use. Whatever else it requires, respect for persons demands that we attend to the unique preferences of each individual. Regardless of whether empirical data show that *most* subjects want results or not, as long as we know that even one may, researchers would be obligated to offer results to all in search of that one.

Once we leave that framework, however, empirical data can play a larger role. First, they can inform the protocols of researchers who admirably want, and are able, to honor subjects' preferences by suggesting whether — and how — to return results. Many who argue that researchers have no ethical *obligation* to return most results further argue that most results *ought* not be offered (Ossorio 2006; Parker 2006). Though I cannot defend this claim here, I would argue that, especially in light of subjects' apparent preferences, researchers ought to move cautiously in the direction of returning most results. Subjects have interests in receiving a much wider range of results than is often acknowledged, and most of the psychosocial risks they are said to face from disclosure remain speculative. Despite the complexity and uncertainty of much genetic information, subjects — once educated — are best positioned to determine whether the potential benefits of learning results, including those of currently uncertain validity and utility, outweigh the risks.

The second role for subjects' preferences is the one Murphy and colleagues (2008) themselves press: returning results may help researchers recruit and retain subjects. As the authors note, their study did not measure the weight that respondents gave to an offer to return results relative to other incentives. Moreover, preferences are constructed in the course of elicitation (e.g., Slovic 2000). It is not surprising that respondents replied in the affirmative when asked whether, all things being equal, they would like to be offered results. But these same respondents, when confronted with an offer to volunteer for research that does not include this option, or with evidence that the price of returning results may be less research, may exhibit different "preferences." In a recent online survey, for example, 84% of AOL customers said they valued privacy and would not give income information online; however, when asked later in the same survey to indicate their income bracket, 89% did so

(AOL 2008). Nevertheless, surveys are a good starting point in gauging willingness to volunteer with or without various incentives.

Arguments, based on subjects' preferences, that researchers *ought* to offer results out of supererogation or prudence are not the same as arguments that they *must* do so, and the distinction is worth preserving. If bioethicists insist on turning their own preferences into obligations for researchers, then researchers unable to meet such standards may either conduct less research, or throw the ethical baby out with the bathwater, deciding that all bioethical pronouncements are unrealistic and eschewing clear obligations like ensuring truly voluntary, informed consent. Neither result would be good for research subjects or society. ■

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Public Expectations for Return of Results—Time to Stop Being Paternalistic?

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There is increasing evidence that research participants for the most part wish to be offered research results (Fernandez et al., in press; Partridge et al. 2003; Shalowitz and Miller 2008). It is clear that offering a summary of results not only

is a sign of respect for persons but also highlights their contribution (Fernandez et al. 2003). This desire for an offer of results is again confirmed in the focus group study by Murphy et al (2008). They find in this well-designed study

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