

## **When Do Genetic Researchers Have a Duty to Recontact Study Participants?**

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Accepting the proposal by Ravitsky and Wilfond (2006) to adopt a “result-evaluation approach” would likely increase the number of studies that returned genetic test results to participants. Furthermore, this approach would represent a shift away from the customary methods of genetic research (not returning results) towards the approach used for provision of genetic tests in a clinical setting (i.e., trained genetic counselors returning results generated in Clinical Laboratory Improvement Amendments (CLIA)-certified labs). Based upon the principles of beneficence, nonmaleficence and respect for persons, we will argue that when researchers adopt roles traditionally held by clinicians, they must also accept the duty to recontact study participants when new information is discovered. We content that this obligation exists regardless of whether or not the genetic test results were disclosed to research participants, and suggest that the threshold of what is considered reportable information should be lower if participants know their genetic test results.

The ethical foundations of the duty to recontact have been debated in the context of clinical care (Hunter et al. 2001; Knoppers 2001), but the principles apply to researchers who return genetic results as well. When developing ethical

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protocols that respect research participants, researchers have a duty to maximize benefits and minimize harms. Since recontacting participants and offering them improved information may result in benefits and also may avoid harms (e.g., participants making healthcare and lifestyle choices based upon outdated information), these principles argue in favor of recontacting study participants when new findings are relevant to their wellbeing. Additionally, recontacting participants demonstrates respect for participants who have put their trust in the research enterprise. Clearly, the implications of recontacting will vary considerably in the context of different research protocols, and decisions will need to take these unique needs into consideration.

Examples of the complexities that need to be addressed are demonstrated in a protocol that uses new genetic research technologies to study more than a single genetic variant at a time. Imagine future research that will involve testing 2,000 participants for 100 genetic markers that may increase the risk for adult-onset chronic diseases. The testing is done in a CLIA-certified laboratory, and the results are analytically valid. Using the framework described by Ravitsky and Wilfond (2006), the researchers choose to report the results for 60 of the markers to the study participants because current evidence demonstrates that these markers may have clinical validity (determining their clinical utility is one of the goals of the research). Significant efforts are made to provide post-test counseling for participants about the meaning of these results. The evidence for the other 40 tested markers do not meet an established threshold, so participants are not informed about these results; however, researchers anticipate that many

of these markers will eventually meet their established criteria for clinical validity. What are the researchers' obligations to recontact study participants as new information emerges about one or more of these 100 markers?

Given this type of scenario and applying the principles described above, we suggest that a researcher's obligation to recontact research participants will depend upon the following factors: 1) whether the test results were initially reported to the participants; 2) the level of potential benefit and risk of harm of the new information; 3) the length of time since testing; and 4) the burden of recontacting participants and conveying this information.

### **1. Whether the test results were initially reported to the participants.**

When participants are given test results along with an interpretation of those results, they develop an understanding of their level of risk for disease. Participants may use this information to mitigate these risks (e.g., modify their lifestyle). If new research demonstrates that what was conveyed to participants about the meaning of the test or the steps to mitigate this genetic risk are discovered to be incorrect, there is a stronger duty (based on the principle of nonmaleficence) to update that information than if the participants know nothing about their test results.

### **2. The level of potential benefit and risk of harm of the new information.**

Determining whether new genetic information passes the threshold where a researcher has a duty to recontact depends upon whether the participant was

aware of the outdated results. In cases where the genetic results were not originally reported, a researcher's responsibility to recontact participants would be limited to information that was deemed highly important (i.e., likely to save lives or prevent serious illness). However, if the researcher has already reported results to participants, determining the threshold for recontacting would be subject to an evaluation process. We suggest that a panel of experts, which includes researcher participants from the study, review the new evidence to determine whether or not it warrants recontacting participants. The standard should be new information that research participants might want to know, not just what researchers have determined is relevant. It is possible that during this evaluation, it may be determined that the new information would produce more harm than good, and, therefore, be in the best interest of participants *not* to recontact them (e.g., discovery of non-paternity). Many of the concepts developed in Ravitsky and Wilfond (2006), Hunter et al. (2001), and Holtzman and Watson (1997) will be useful in formulating careful decisions about this threshold in the context of a particular research protocol.

### **3. The length of time since testing.**

It would impose too great a burden on the research enterprise to argue that the researcher's obligation to recontact participants with new information extends indefinitely. Protocols close, data are eventually destroyed, and primary investigators change jobs and even die. Additionally, some genetic research is conducted with the ultimate goal of applying this information in clinical practice.

Eventually, primary-care providers may take over the role of keeping their patients informed about new findings. Therefore, limiting the researcher's obligation to recontact participants, and stating this limit in the informed consent protocol, is reasonable. The local institutional review board (IRB) can help determine whether the proposed timeframe is adequate. Many protocols may require follow-up of five to ten years or even longer.

#### **4. The burden of recontacting participants and conveying this information.**

Cost alone is an insufficient reason not to recontact research participants, but it is a burden that researchers planning genetic studies need to consider. It is nearly impossible to predict the type of new information that may become available and budget for the possibility of having to recontact participants. In our hypothetical research scenario, it would require: 1) analyzing information on 60 genetic markers; 2) being aware of major developments with clinical implications for an additional 40 markers; 3) ensuring that new information was presented to participants in an understandable format; 4) offering appropriate genetic counseling; and 5) tracking a large cohort over time. All of these activities require considerable resources, perhaps to the detriment of other research activities. The lower the threshold is drawn requiring researchers to return results and the greater the number of genetic markers that are tested, the higher the burden of recontacting participants is likely to become.

Although there is unpredictability in the new genetic information that could emerge over time, researchers should, nevertheless, create a plan for recontacting research participants and clearly describe this plan in the informed consent protocol. Researchers may want to consider putting a provision in the consent protocol where participants may “opt out” of any follow-up contact. When recontacting participants is warranted, there are a number of communication strategies that may be appropriate depending upon the type of information being conveyed.

We think that Ravitsky and Wilfond’s (2006) framework for deciding whether results should be returned to research participants is useful; however, we conclude that researchers’ responsibilities extend even further and necessitate recontacting study participants when new information passes an established threshold of importance. Assessments that weigh the ethical balance of obligations to research participants against the realities of research resources must take this duty into account.

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