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'Recruitment by genotype' for genetic research poses ethical challenges, study finds

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(Garrison, NY) A potentially powerful strategy for studying the significance of human genetic variants is to recruit people identified by previous genetic research as having particular variants. But that strategy poses ethical challenges to informed consent, as well as potential risks to the people recruited, and it is unlikely that there is a "one-size-fits-all" solution, concludes an article in *IRB: Ethics & Human Research*.

The advantage of "recruitment by genotype" is that it eliminates the time-consuming, expensive process of screening new populations to find subjects who have the genetic variant of interest. The ethical challenge is that it requires the disclosure to individuals of genetic information discovered about them in prior research – for example, research on tissue samples that they donated for scientific study. Such information can carry risks and harms because it is often preliminary and easily misinterpreted, and it may be unwanted by some individuals. But without this information, potential participants would be uninformed about why they are being recruited for the new study.

As the first step toward developing ethical guidelines on genotype-driven recruitment, the authors conducted an online survey of 201 chairs of institutional review boards (IRBs). The survey asked a series of questions about 1) the conditions that should be met before recontacting individuals for genetic research recruitment, and 2) whether individuals' genetic research results from the first study should be disclosed as part of the recruitment process for the second study.

The responses were diverse and in some cases contradictory. Only 37 percent of IRB chairs agreed with the general statement, "Researchers should be allowed to contact participants in one genetic research study in order to invite their participation in another genetic research study." But more detailed questions revealed greater willingness of permit contacting of participants if certain conditions were met. For example, 91 percent said that it would be important that the possibility of such contact was disclosed during the consent process for the first study.

However, when the researchers presented the respondents with a hypothetical scenario in which the original consent form did not mention the possibility of contact about future research, 51 percent of the IRB chairs said they definitely or probably would allow the researcher to contact eligible participants anyway. The findings suggest that while consent disclosures are important and highly preferable, "not all chairs necessarily view them as imperative," the authors concluded.

There was a similar variation in response to questions about offering people information about their genetic results from previous studies. Only 42 percent of IRB chairs agreed with the general statement, "Each participant should be offered his/her individual genetic results from the first study when contacted about taking part in the second study." But most said that specific conditions would be important in determining whether it was ethically acceptable to reveal that information: 87 percent of respondents said that statements in the consent form for the first study concerning disclosure of individual genetic research results would be important, 86 percent cited the level of clinical validity (defined as "the accuracy with which the presence of a gene variant predicts the presence of a clinical condition or predisposition"), and 76 percent cited the level of clinical utility (defined as "the availability and effectiveness of interventions aimed at avoiding the adverse clinical consequences of a gene variant").

The survey concluded with questions about specific ethical dilemmas involved in genotype-driven research recruitment. For example, asked to weigh the value of avoiding disclosure of genetic information with uncertain clinical utility against the value of promoting participants' autonomy in determining the utility of the information, 46 percent chose disclosure and 39 percent chose autonomy.

"A major consequence of these findings is that it is unlikely that there will be a "one-size-fits-all solution, but rather several approaches to genotype-driven recruitment that may be ethically acceptable depending on a variety of context-dependent factors," the authors concluded. The two strongest context-dependent factors identified in the survey were 1) disclosure made during informed consent for the original study, and 2) the clinical validity (and, to a slightly lesser degree, the clinical utility) of the information.

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