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Researcher Practices on Returning Genetic Research Results

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Background/Aims: As genetic and genomic research proliferates, debate has ensued about returning results to participants. In addition to consideration of the benefits and harms to participants, researchers must also consider the logistical and financial feasibility of returning research results. However, little data exist of actual researcher practices. *Methods:* We conducted an online survey of 446 corresponding authors of genetic/genomic studies conducted in the United States and published in 2006–2007 to assess the frequency with which they considered, offered to, or actually returned research results, what factors influenced these decisions, and the method of communicating results. *Results:* The response rate was 24% (105/446). Fifty-four percent of respondents considered the issue of returning research results to participants, 28% offered to return individual research results, and 24% actually returned individual research results. Of those who considered the issue of returning research results during the study planning phase, the most common factors considered were whether research results were deemed clinically useful (18%) and respect for participants (13%). Researchers who had a medical degree and conducted studies on children were significantly more likely to offer to return or actually return individual results compared to those with a Ph.D. only. *Conclusions:* We speculate that issues associated with clinical validity and respect for participants dominated concerns of time and expense given the prominent and continuing ethical debates surrounding genetics and genomics research. The substantial number of researchers who did not consider returning research results suggests that researchers and institutional review boards need to devote more attention to a topic about which research participants are interested.

Introduction

Over the last few years, the issue of returning research results to participants has been the subject of much debate, spurring a number of recommendations, particularly with respect to genetics and genomics research (Bookman *et al*., 2006; Knoppers *et al*., 2006; Renegar *et al*., 2006; McGuire *et al*., 2008; Shalowitz and Miller, 2008). Questions about whether and how to return personal and aggregate results are especially challenging for genetic and genomic researchers because of the technical complexity of the research as well as the data and the oftentimes uncertain clinical interpretation of the data (Sharp and Foster, 2006).

In general, research participants are interested in receiving research results (Snowdon *et al*., 1998; Partridge *et al*., 2003; Richards *et al*., 2003; Fong *et al*., 2004; Moutel *et al*., 2005; Fernandez *et al*., 2007; Murphy *et al*., 2008). Participants have indicated that they desire access to research results even if the data are upsetting (Schulz *et al*., 2003) or not considered clinically valid or useful (Wendler and Emanuel, 2002), whereas others indicated they desired to learn only of results that were clinically useful (Hoeyer *et al*., 2004). Researchers may opt to return individual or aggregate (i.e., summary) results (Miller *et al*., 2008). Aggregate reports would be the only way to inform participants of a study's outcome if the samples were collected anonymously or pooled. However, aggregate reports may dilute the value of results because participants will be unsure of the findings' individual significance (Dixon-Woods *et al*., 2006). Disclosure of summary research results, even those of a serious nature or negative results, has generally not been found to result in adverse psychological impacts in research participants although a subset of participants has experienced negative effects such as feelings of fear, guilt, and anxiety (Bunin *et al*., 1996; Snowdon *et al*., 1998; Schulz *et al*., 2003; Partridge *et al*., 2005, 2009).

Those who support providing participants with the option to learn of their results, either individual or aggregate, argue that it shows respect for participants and re-positions them as active contributors to research studies as opposed to being only a means of accomplishing research (Shalowitz and Miller, 2005; MacNeil and Fernandez, 2006). However, the results could be harmful if participants misinterpret or overestimate the significance of the findings (Bunin *et al*., 1996). In addition, offering to return results may strain already limited

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resources for researchers due to the extra costs, labor, and time required to re-contact study participants and validate results in a Clinical Laboratory Improvement Amendment–certified laboratory (Dixon-Woods *et al*., 2006; Shalowitz and Miller, 2008).

A number of groups and individuals have developed criteria regarding returning research results. In general, the recommendations have emphasized the importance of clinical relevance and utility of the data when deciding whether to disclose it (National Bioethics Advisory Committee, 1999; Shalowitz and Miller, 2005; Bookman *et al*., 2006; MacNeil and Fernandez, 2006). For example, the National Bioethics Advisory Committee (1999) recommended that, to be disclosed, results must not be harmful to participants and be clinically useful (Shalowitz and Miller, 2005). The National Heart, Lung and Blood Institute Working Group (Bookman *et al*., 2006) and Stanford Working Group on Reporting Results of Genetic Research (2005) both identified the availability of a clinical intervention, either for prevention or for treatment, as a key criterion for offering to return individual results. Although the recommendations have not been implemented in regulations, the issue has remained at the forefront of human subjects' research, particularly for genomics research (McGuire *et al*., 2008).

Despite the attention given to this issue, to our knowledge, few data have been collected regarding the prevalence of returning research results, although some studies suggest that the practice is uncommon (Partridge *et al*., 2004; Rigby and Fernandez, 2005; Shalowitz and Miller, 2008). To provide insight on the practices of genetic and genomic researchers regarding disclosure of research results to participants, we conducted an online survey of authors of genetics and genomics articles published in 2006 and 2007. We hypothesized that the major reasons for not providing the option to return results were cost, time, and the uncertain clinical significance of the results. We also hypothesized that researchers were less likely to return results if the study included minors, received a majority of its funding from industry or private sources, or occurred outside of an academic medical center or hospital. Our data identify several factors important in the consideration and return of research results that warrant further study.

Methods

Survey development

Based on a review of the literature on returning research results, we developed a short online survey (14 questions) (see Table 1). Specifically, we assessed whether genetic and genomic researchers considered the issue of returning individual research results, the factors considered in this decision, and the practice of offering to return or actually returning aggregate and individual results. All multiresponse questions included a write-in "Other" answer category to allow participants to provide additional responses if given answer categories were not suitable. The survey was reviewed by colleagues (not part of this study) at the Center for Genome, Ethics, and Law at the Duke Institute for Genome Sciences and Policy and revisions made accordingly. An online password-protected survey was designed using Survey Monkey (www.surveymonkey.com). The survey was anonymous; neither the hosting site nor we could trace participants' IP addresses or associate e-mail addresses with particular responses. This study was approved by the Duke University Medical Center's Institutional Review Board (IRB).

Table 1. Outline of Survey Questions

Independent variables (study/researcher)	*Practices*
Study characteristics Disease type Funding source Location Inclusion of children	Consideration (and reasons for/against) of returning individuals results
Researcher characteristic Highest degree	Offering to return (and reasons for) individual research results Returning individual research results Type of result returned Method of communication Returning aggregate research results

Survey population

To identify our sample population, we performed a search in PubMed of articles published in 2006 and 2007 using search terms such as "genetic structure," "genetic processes," "genetic phenomena, "genetics," and "association." We limited our search to the 10 top-ranked genetics journals (defined by impact factor) and to PubMed's core clinical journals (119 journals; see www.nlm.nih.gov/bsd/aim.html for complete list). In addition, we limited our search to original research articles and authors with a U.S. affiliation due to different national rules and regulations for human subjects research. All abstracts were manually reviewed to ensure that studies met our inclusion criteria and involved study of genetic variation (DNA or RNA) linked to a disease phenotype in a U.S.-based study population (studies of biobanked samples and human cell lines were excluded). The initial PubMed search yielded 987 articles for 2007 and 879 articles for 2006. After manual review, 236 articles from 2007 and 252 articles from 2006 matched our criteria. An e-mail address for the corresponding author listed was obtained from the author address field in PubMed; if none was provided, a manual search of the author's affiliation or other publications was performed to obtain an e-mail address.

Recruitment

An e-mail invitation was sent to corresponding authors describing the purpose of the study along with the survey URL and password. Since a number of researchers were listed as corresponding authors on more than one publication between 2006 and 2007, we included the citation for the study of interest in the e-mail. Two follow-up e-mails were sent to encourage participation in the survey and thank those who had already participated at 10 and 24 days after the initial invitation. Participants were presumed to have consented to the survey if they initiated the survey by clicking "Next" on the first page,

which provided information about the purpose, risks, and benefits of the study. No compensation was provided.

Data analysis

Summary statistics were generated for each question; descriptive data were expressed as a percentage or mean. Fisher's exact tests were conducted to assess the relationships between the dependent variables (considered returning individual research results, offered to return individual research results, and actually returned individual research results) and independent variables (disease category, inclusion of minors, returning summary results, funding type, type of institution, and highest degree of researcher). To enable analysis of questions in which respondents could select multiple answers, we converted multianswer responses into binary responses indicating whether or not a respondent selected a particular answer. Several questions allowed respondents to write in answers; these answers were either grouped into standing answer categories or placed into an "other" category relating to the respective question. Because we tested multiple hypotheses and wished to minimize our false discovery rate, a Type I error probability of 0.01 or less was considered statistically significant. At this level, and given the number of hypothesis tests run, we expected to see 0–2 false discoveries.

To determine if respondents were representative of the sample population, we collected data on the inclusion of minors, disease type, and highest degree of corresponding author for the entire sample population. We also collected information on funding source, but since many studies listed multiple sources, it was not possible to identify the primary funding source as asked in the survey. Based on a test of proportions, we found no difference between respondents and nonrespondents in the rate of inclusion of minors nor in diseases studied (see Supplemental Table S1, available online at www.liebertonline.com). The survey response rate shows a borderline association with highest degree ($p = 0.03$) with M.D.'s slightly less likely to respond than Ph.D.'s, but this is not significant at our study-wide significance level of 0.01. Thus, we do not believe that there are any statements in the article that would be invalidated by this association.

Results

Subject/reference study characteristics

Four hundred eighty-eight researchers were invited to participate in the survey. Forty-two e-mails were returned with no forwarding address. Out of 446 researchers reached, 105 (24%) completed the survey.

Because we did not link survey responses to respondents' identities or publications, we asked some descriptive questions about the study in question (Table 2). In reference to their publication, the majority of respondents (83%) indicated that their study was performed at a university or other academic medical center. The major sources of support were federal funds (76%), and more than one-fourth of the studies (28%) involved participants under the age of 18 years. Respondents were almost evenly divided by their terminal degrees between Ph.D., M.D., and M.D./Ph.D. Neoplasms were the most frequently studied disease (19%), followed by diseases of the nervous system (13%) and the circulatory system (12%).

Table 2. Characteristics of Researcher and Research Study of Interest

Characteristic (n = *105*)	n *(%)*
Study included minors	29 (28)
Type of funding support	
Federal	80 (76)
Internal	14 (13)
Private	11 (11)
Primary location of study	
University/academic medical center	87 (83)
Hospital (nonuniversity affiliated)	4 (4)
Research Institute	10 (9)
Other (federal government, foundation hospital)	4 (4)
Highest degree of corresponding author	
Ph.D.	35 (33)
M.D.	35 (33)
M.D. and Ph.D.	31 (30)
Other professional doctorate	3 (3)
Master's	1 (1)
Disease studied[a]	
Neoplasms	24 (19)
Nervous system	17 (13)
Circulatory system	15 (12)
Blood and blood-forming organs	12 (10)
Endocrine, nutritional/metabolic, immune system	11 (9)
Musculoskeletal/connective tissue	9 (7)
Mental	8 (6)
Respiratory	8 (6)
Digestive	7 (6)
Other	15 (12)

[a]Total does not equal 105 as respondents could indicate more than one disease.

Considering returning results

We asked researchers whether they considered the issue of returning results during the planning stages of the study and if so, what factors were specifically considered. A slight majority of respondents (54%) considered the issue of returning research results (type of result—individual or aggregate—not specified) to participants. Of those who considered returning results, the most common factor considered was whether the research results were deemed clinically useful (18%), followed by respect for participants (13%) (Table 3). Additional factors included the availability of a Clinical Laboratory Improvement Amendment–certified lab to verify results (12%), and ethical or legal concerns about re-contacting participants (11%). Respondents with an M.D. were more likely to select "research result was deemed clinically useful" as a consideration (odds ratio [OR] 5.4; $p = 0.01$; 95% confidence interval [CI] 1.3–25.2).

Of those who did not consider returning research result during the planning stages, the uncertainty of the result was the primary reason with 35% indicating that data or results were considered preliminary and unvalidated. Almost a quarter of respondents (23%) indicated that the option to return research results was not even raised during the planning stages. Seventeen percent indicated that they could not return results because participants were anonymous or samples were pooled. Additional reasons offered by respondents (via the write-in option) included IRB-imposed restrictions on returning results and that the study was considered as research and/or designed for research purposes, and therefore

Table 3. Primary Reasons Indicated in Consideration/No Consideration of Issue to Return Research Results

Considered returning research results (n = 57)		*Did not consider issue of returning research results* (n = 48)	
Why? (%)		*Why not? (%)*	
Results were deemed clinically useful	42 (18)	Results were deemed preliminary and unvalidated	17 (35)
Respect for participants	31 (13)	Other—patients died, IRB issues, lack of CLIA-certified lab	12 (25)
Availability of CLIA-certified lab to verify results	28 (12)	The option to return results was not raised	11 (23)
Ethical or legal concerns about re-contacting the participants	25 (11)	Participants were anonymous or samples were pooled	8 (17)

CLIA, Clinical Laboratory Improvement Amendment; IRB, Institutional Review Board.

providing the option to return results would be inappropriate. No associations were detected between researcher degree or study characteristics.

Offering to return individual research results

Overall, 29 respondents (28%) indicated that they offered to return individual research results to participants, and 27 of those respondents indicated that they had considered whether to return individual results during the planning stages of the study. Of those who offered to return individual results, the most common reasons noted were the perceived clinical relevance of research results (62%), followed by respect for participants (31%). Only one respondent indicated that time was a significant factor and three indicated that cost or available budget influenced their consideration. Respondents who offered the option to return individual results were slightly more likely to have considered respect for participants (OR = 3.5; $p = 0.03$; 95% CI 1.0–12.5) and believed that the results were clinically useful (OR = 5.2; $p = 0.02$; 95% CI 1.2–32.8) when deciding to make the option available.

Researchers of studies that included children were significantly more likely to have offered to return individual results (OR 3.7; $p < 0.01$; 95% CI 1.4–10.5) (Table 4). Researchers with an M.D. were also more likely to offer to return individual results, though not significant (OR 2.8; $p < 0.05$; 95% CI 0.95–9.3). Researchers of studies of endocrine, nutritional, and metabolic diseases and immunity disorders (OR 5.6; $p = 9.4e\text{-}3$; 95% CI 1.29–28.7) and diseases of blood and blood-forming organs (OR 4.44; $p = 0.018$; 95% CI 1.09–19.7) were more likely to offer to return individual results.

Actually returning individual research results

Overall, 25 respondents (24%) indicated that they actually returned individual research results to study participants. Of those who offered to return individual results, 83% (24/29) subsequently returned individual results to some participants (i.e., one of the respondents did not offer to return individual research results, but ultimately did so). All 25 respondents who returned individual results also considered the issue of returning results during the study planning stages.

Of the respondents who returned individual research results, 56% returned all results (e.g., positive and negative) and 44% returned only results indicating increased risk. Results were most commonly returned via a genetic counselor, social worker, or other trained counseling professional (48%), followed by telephone (40%), postmail (40%), in-person (32%), the referring doctor (32%), and e-mail (8%) (percentages total >100% as some respondents indicated multiple methods). On average, 2.7 modes of communication were used. No association was detected between type of result returned and mode of communication, disease type, or researcher degree.

Researchers with an M.D. were significantly more likely to have actually returned individual research results to participants (OR 5.6; $p < 0.01$; CI 1.5–31.7). Researchers of studies that included children were also significantly more likely to actually return individual results (OR 2.7; $p < 0.01$; 95% CI 0.93–7.7). In addition, researchers of studies of diseases of blood and blood-forming organs (OR 5.7; $p < 0.01$; 95% CI 1.38–25.7) and endocrine, nutritional, and metabolic diseases and immunity disorders (OR 7.2; $p < 0.01$; 95% CI 1.63–37.3) were significantly more likely to actually return individual results.

Twenty percent (21/105) of all respondents provided summary results via newsletter, Web site, or other "public" method. Of these, 66% (14/21) had considered the issue of returning individual research results during the planning stages of the study (data not shown; not significant). Only two respondents returned both summary and individual results. No associations were identified between researcher or study characteristics and returning summary results.

Discussion

Numerous issues may influence the decision of whether researchers return research results to study participants. Not only must researchers weigh the benefits and harms to the research participant, but they must also consider the logistical and financial feasibility of returning results safely and appropriately. Our study provides some important insights on researcher practices on the issue of returning results.

The National Bioethics Advisory Committee (1999) recommended that IRBs require investigators to address whether and how to return individual research results in their study proposals. At this early stage, researchers can appropriately address the issue during the informed consent process and ensure that adequate resources are allocated for trained staff to return results to interested participants. However, our finding that a substantial number did not consider the issue (46%), slightly higher than a previous survey's finding (38%) (Rigby and Fernandez, 2005), suggests that further dialog between researchers and IRBs is warranted. Although IRBs have expressed support for returning research results (MacNeil and Fernandez, 2007), IRBs may

Table 4. Associations Between Researcher/Study Characteristics and Consideration, Provision of Option, and Actual Return of Results

	Considered returning results		*Provided option to return results*		*Actually returned results*	
	Yes (n = *57*)	*No* (n = *48*)	*Yes* (n = *29*)	*No* (n = *76*)	*Yes* (n = *25*)	*No* (n = *80*)
Disease						
Neoplasm	13	11	7	17	3	21
Nervous system	11	6	7	10	5	12
Circulatory	7	8	2	13	2	13
Blood and blood-forming organs	8	4	7[a]	5[a]	7[b]	5[b]
Endocrine, nutritional, metabolic, immune system	7	4	7[b]	4[b]	7[b]	4[b]
Musculoskeletal/connective tissue	4	5	2	7	2	7
Mental	2	6	1	7	0	8
Respiratory	3	5	1	7	1	7
Digestive	2	5	1	6	1	6
Other	10	5	2	13	3	12
Included minors	19	10	14[b]	15[b]	11[a]	18[a]
Provided summary of results	13	8	3	18	2	19
Funding source						
Federal	44	36	18	62	15	65
Internal	7	7	6	8	5	9
Private	6	5	5	6	5	6
Degree of researcher						
Has M.D. (M.D. or M.D./Ph.D.)	36	30	23[a]	43[a]	22[b]	44[b]
Ph.D. or other (M.A.)	21	18	6	33	3	36
Academic institution						
University	47	39	25	61	21	65
Hospital	2	3	1	4	1	4
Research institute	7	4	2	9	2	9
Other (government, foundation)	1	2	1	2	1	2

Statistical tests are for associations between response (yes/no column headers) and corresponding category.
[a] $p \leq 0.05$.
[b] $p \leq 0.01$.

need to be more proactive in raising the issue with researchers, perhaps by asking researchers to indicate if the issue was considered in the IRB application materials, and provide general guidance. A previous survey of researchers found that those who had a plan for returning individual research results were more likely to have an IRB that mandated such action (Rigby and Fernandez, 2005). One possible approach to raise awareness is to incorporate information about returning research results into educational modules to fulfill human subjects' certification requirements. Nationally led efforts may be needed, however, to address the lack of or inconsistency of existing IRB guidelines in the United States on this subject (Kozanczyn *et al*., 2007).

Although previous studies identified cost and time as barriers to returning research results (Fernandez *et al*., 2003; Miller *et al*., 2008), we found that only a minority of researchers who considered returning results during the planning stages of the study indicated that these factors affected their decision. We speculate that issues associated with clinical validity and respect for participants dominated concerns of time and expense given the prominent and continuing ethical debates surrounding genetics and genomics research, potential family implications, and participant interest. In addition, the size of the study in which returning results was considered or occurred may have been smaller and thus more feasible. Researchers with medical training were significantly more likely to offer or actually return research results. A number of reasons may underlie the different researcher behavior with respect to returning individual research results. Medically trained researchers who provide clinical care may have a closer relationship to study participants than nonmedical researchers. Other factors that may positively influence medical researchers' decision to return results include participants' vulnerability and uncompensated risks or burdens (Belsky and Richardson, 2004). Any combination of these factors may increase the obligation or duty of care to return research results, although these factors are not unique to medical researchers. Previous studies indicated that a substantial proportion of health professionals involved in research supported returning results to participants (Garcia, 1987; Fernandez *et al*., 2003; Partridge *et al*., 2004).

Our finding that researchers were more likely to offer to and actually return results in studies with minors was at odds with our prior hypothesis. Although this finding comports with the strong interest that minors and their parents have expressed in receiving aggregate and individual results in previous studies (Fernandez *et al*., 2005, 2007, 2009), we had speculated that the higher potential for harm and, therefore, a higher risk:benefit ratio might discourage researchers from returning results to children. We also found that clinical usefulness and respect for participants were considered by the majority of researchers whose study populations included

minors, further supporting the conclusions of Fernandez *et al.* (2009) about the participant's importance to the study or research in general.

Our study has some limitations that should be considered. In addition to the small sample size, our findings may reflect response bias as researchers familiar with this issue might have been more inclined to participate in the survey. As such, we speculate that a smaller proportion of genetics and genomics researchers might regularly consider offering research results in the planning phases of their research, and an even smaller number actually return results. A systematic assessment of all genetics and genomics research studies conducted at several institutions may provide a more accurate estimate of the scope of consideration and actual return of research results. As the findings were limited to researchers of genetic and genomic studies and, the data may not be generalizable to other types of research.

Our study provides an initial analysis regarding the practices of genetics/genomics researchers about returning research results. While researchers often considered the clinical and ethical risks and benefits of returning results, IRBs and policymakers need to continue to increase researchers' awareness of the issue. Continuing researcher education modules or seminars on returning research results, requiring researchers to indicate that they have considered this issue on an IRB submission checklist or within the study protocol and informed consent document, and development of a FAQ for researchers could all improve awareness of this issue. Further, journals may consider asking authors to indicate if results were returned to participants. As more studies include genetic/genomic analyses in their protocols, researchers will undoubtedly be confronted with a wide array of interest and responses from study participants, thus making it imperative that researchers, IRBs, scholars, and policymakers collaborate to develop uniform guidelines regarding returning research results. In addition, the evolving view of participants as partners in research may raise participants' expectations for access to research results and a voice in deciding when access should be limited or denied. If genetic and genomic research is to receive the public support needed to recruit thousands of participants for a single study, then researchers may need to re-consider the role participants have in the study and clearly explain that role to potential participants, whose own interests cannot be taken for granted.

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