

**Return of Individual Research Results: A Survey of Genetic Counselors'
Opinions and Experiences**

Master's Thesis

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by
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Abstract

Return of Individual Research Results: A Survey of Genetic Counselors' Opinions and Experiences

A thesis presented to the Department of Biological Sciences: Genetic Counseling

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The return of individual research results (IRRs) has become a controversial topic within the genetics research community. Despite published policy papers and professional symposia on this issue, little consensus on the process has been achieved. Genetic counselors are the medical professionals often responsible for coordinating disclosure of results in the context of genetic research. However, the attitudes, opinions and experiences of genetic counselors related to disclosure of IRRs have yet to be examined. The goal of this study was to assess the opinions and experiences of genetic counselors regarding the return of research results to study participants. Our hypothesis was that opinions would vary significantly among counselors with respect to both the types of results that should be disclosed and the process to be followed. In particular, we hypothesized that counselors with more experience returning IRRs would feel more strongly in favor of returning these results than counselors with no experience returning IRRs. We also hypothesized that counselors would feel more strongly in favor of returning clinically actionable results than other types of results. We conducted an anonymous online survey of 163 genetic counselors recruited via the National Society of Genetic Counselors

(NSGC) listserv. The survey respondents varied widely in their opinions about and experiences with the process of disclosing IRRs. However, our results showed that genetic counselors were more strongly in favor of returning clinically actionable results and results with reproductive implications. In addition, the provision of informed consent as well as CLIA confirmation were important factors for counselors when considering return of IRRs. Future efforts should focus on developing a consensus among genetic counselors and the research community for recommendations on the process of handling IRRs.

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Introduction

Background on Individual Research Results (IRRs)

An evolving concern of researchers, medical professionals, and the general public is how to handle disclosure of results from genetic research studies. Laws, policies and Institutional Review Boards have so far provided little guidance on this issue (Kozanczyn, Collins, & Fernandez, 2007). This has left the scientific community without a consensus since the legal, ethical, social, and financial considerations are convoluted and complex.

An Individual Research Result (IRR) is a research study finding, generally understood to have health or reproductive significance, or the potential for such significance, for an individual research participant. An Incidental Finding (IF), one type of IRR, is defined as “ a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research but *is beyond the aims of the study* [emphasis added]” (Wolf et al., 2008). An IF may arise because it is now possible and some argue, more economical and efficient, to look at thousands of genes simultaneously or even a person’s entire genome, rather than a defined subset of genes as done in the past. Dr. Kohane, a researcher and professor at Harvard Medical School, even coined the term “incidentalome” to describe the wealth of information and complete collection of incidental findings within a genome study (Kohane, Masys, & Altman, 2006). Current technology now provides an opportunity for the identification of many

different types of IF's in multiple genes (Clayton, 2008), the significance of which may not be readily apparent. In addition, IF's can also be classified into different categories including those with analytic validity, clinical utility, actionability, and/or variants of uncertain significance (VUS) (Fabsitz et al., 2010), so even the term 'incidental finding' is open to interpretation. Thus classification and utilization of IRRs is a complicated issue in itself, confounding the process of returning to participants individualized feedback from genetic research studies.

Factors in the return of IRRs

Members of the research community as well as the public have expressed an interest in allowing disclosure of IRRs to participants, though this was not routinely performed in the past. One study assessing the opinions of parents of children with autism regarding the return of research results found that 97% of respondents wanted to learn of research results, and 79.7% held researchers responsible for providing the results (Baret & Godard, 2011). The general public is also interested in learning of *individual* research results, not just the aggregate findings of a study. One study, utilizing focus groups to assess the public attitude regarding this issue, concluded that the majority of individuals, while recognizing the complexity of the situation, valued the return of individual research results and cited a lack of results disclosure as a deterrent to research enrollment and participation (O'Daniel & Haga, 2011). Participants of ClinSeq, (Biesecker et al., 2009), a GWAS study designed to explore how to return IRRs to participants, also cited interest in receiving individual research results. Indeed, the majority of ClinSeq participants were motivated to participate for two primary reasons: the altruism of contributing to research and the

desire to learn of personal health information, risks and genomic information (Facio et al., 2011).

Meacham et al. (2010) conducted a study assessing the researcher perspective on return of IF's utilizing hypothetical vignettes and found that the majority of researchers would disclose IF's (Meacham, Starks, Burke, & Edwards, 2010). Several considerations and qualifications were cited as important to the disclosure decision including analytic validity, and result confirmation in an authorized, clinically certified lab. Researchers also cited ethical consideration of participant welfare as a motivation for allowing results disclosure.

A complicating factor in this debate is the federally regulated Clinical Laboratory Improvement Amendments (CLIA) legislation. CLIA established standards for clinical laboratories to ensure the analytic validity and accuracy of clinical testing. CLIA regulations include quality control and assurance measures, specimen management standards and proficiency testing criterion for staff as well as other standards that typically do not apply to research laboratories as facilities that do not report out individualized patient results used for clinical care. However, CLIA regulations do apply to any entity conducting a laboratory test within the US and returning results to individuals (CMS, 2011) and in theory, some research labs may wish to pursue this certification, despite being an added burden on labs.

In sum, although most individuals, both those disclosing and those receiving research results, recognize some of the complexities of results disclosure, many express a desire to have results return provided as part of study participation.

Efforts to Clarify Guidelines and to Return IRRs

Historically, individual research results were not routinely returned to participants leading to the current confusion surrounding if or when IRRs should be returned, and what the process should entail. Policy makers and researchers have sought to clarify both issues and most agree that some, but not all research results should be returned. In 2006, an NHLBI working group published recommendations for the return of research results. Their recommendations suggested that genetic results should *only* be returned if the test has analytic validity, if the result involves significant disease risk for a disease which has important health implications, and if proven therapeutic and medical interventions are available (Bookman et al., 2006). In 2009, these recommendations were updated to include the provision that the participant has opted within the informed consent process to receive research results and that the cost of the return of research results does not exceed study funding (Fabsitz, et al., 2010). Although clinical utility is a common context in which many researchers agree that returning a result to a participant would be prudent, clinical utility can be subjective, has no direct measure and can depend on several factors such as quality of the data and analytic validity of the test. Therefore, some researchers still argue in favor of complete disclosure of all research results (Kollek & Petersen, 2011).

Efforts are also underway to develop a consensus regarding *how* research results should be returned, with several models proposed by different groups. The 2009 NHLBI working group recommended that there be a central advisory committee providing input to investigators and IRB's on what research results are

reportable (Fabsitz, et al., 2010). Another model proposed the 'Informed Cohort' design in which subjects are given a web-based personally controlled health record. An 'Informed Cohort Oversight Board' (ICOB) broadcasts the type of result or information available and each participant has an 'agent' which matches the participant to the appropriate broadcasts. Subjects set preferences for their agent as to what type of broadcasts they would like to receive (Kohane et al., 2007).

Wolf et al. (2008) have specifically addressed concerns regarding the Informed Consent process prior to results disclosure. They recommend a complete discussion on the possibility of IRRs and their potential harms and/or benefits as well as the ability of participants to indicate what type of IRRs they would want to know, if any. Furthermore, the principal investigator, research team and the IRB should work together in designating a strategy to handle IRRs and which IRRs are appropriate to give to participants (Wolf, et al., 2008). The existence of various, sometimes conflicting, proposals and recommendations regarding disclosure of genetics research results illustrates the continued need for established consensus recommendations, guidelines and policies addressing this issue.

Role of Genetic Counselors in the Return of IRRs

One important point to consider in the context of navigating research results disclosure is communication between the researcher and participant. Many proposed models and guidelines for disclosure of research results fail to address how the result will be relayed to a participant and who should relay the information. Of the literature that does discuss this issue, most suggest that results be disclosed orally and in person by an individual who has appropriate training and expertise in

human genetics as well as experience dealing with patients and families (Kollek & Petersen, 2011). Oftentimes, genetic counselors are assigned the role of intermediary and interface between patients and the research laboratory (Markel & Yashar, 2004). Despite the fact that genetic counselors are the appropriate individuals to disclose genetic research results and navigate this complex situation, no study has assessed genetic counselors on their views, advice and experiences with the return of IRRs.

Purpose of Study

The purpose of this study was to assess the personal opinions and actual experiences of genetic counselors regarding the return of research results to participants, including the process by which results are returned, in order to determine if a consensus amongst genetic counselors exists.

From the perspective of genetic counselors who have experience returning IRRs, we examined their opinions and experiences in various scenarios involving different categories of research results. Additionally, we determined whether the opinions of these counselors varied from their own real-life experiences and if they also differed from counselors without experience returning IRRs.

Genetic counselors who had never encountered IRRs, and thus had no stated personal experience, were also surveyed to assess whether their opinions differed depending on the scenario or type of result presented; whether their opinions varied from counselors with IRR experience; and what their opinions were of what the results process should entail.

Overall, obtaining information from genetic counselors about their opinions and experiences regarding the return of research results could provide insights about pertinent issues, identify potential challenges and allow genetic counselors and researchers to move closer to developing a consensus and standard practice when handling research results disclosure.

Hypotheses

Given the varying opinions found in guidelines and consensus documents discussed above, it could be suggested that genetic counselors' opinions would also vary significantly from each other depending on numerous factors. Researchers, or those who have experience with IRRs, have generally been in favor of returning research results (Meacham, Starks, Burke, & Edwards, 2010). Additionally, many of the consensus documents have stressed the importance of 'clinical utility' when considering disclosure, as well as confirmation of such result in a CLIA certified laboratory (Fabsitz, et al., 2010) and these criteria are not always easily obtained for novel research findings. Current recommendations also vary significantly on the optimal process for IRR disclosure (Fabsitz, et al., 2010; Kohane, et al., 2007; Wolf, et al., 2008). Given this, one would not necessarily expect the genetic counseling community to differ from the research community at large.

Therefore, our hypotheses for the study were as follows:

- 1) Opinions regarding IRR disclosure would vary significantly between counselors; specifically, counselors with more experience with IRRs would feel more strongly in favor of returning IRRs than counselors with no experience.

- 2) Genetic counselors' opinions would significantly vary on the actual process of returning IRRs.
- 3) Genetic counselors would feel more strongly in favor of returning results with 'clinical utility', or clinically actionable results, than other types of results.

Materials and Methods

Study Design

This study was a cross sectional quantitative study of genetic counselors. This project received human subjects approval from the Brandeis University Institutional Review Board.

Sample and Recruitment

Genetic counselors were eligible to participate in the survey regardless of practice setting. Participants were recruited online with a recruitment notice posted on the listserv of the National Society of Genetic Counselors (NSGC) (Appendix A). The recruitment notice contained information about the research study including the study aims, eligibility criteria and the process of study participation. The notice also specified that survey participation was voluntary, anonymous and confidential and provided a link to the online study survey.

Data Collection Procedures

Data was collected through an anonymous online survey, via Qualtrics (Appendix B). The survey elicited opinions regarding IRR disclosure and also collected limited demographic information. Upon completion of the survey, participants were redirected to another website to voluntarily enter their email address for the chance to win one of two \$50 gift certificates to Amazon.com. Participants were reminded that their personal information would not be linked to their survey responses.

The study survey consisted of Likert scale, multiple choice questions and open-ended free response questions. Definitions for the terms used in the survey were also provided.

Participants were asked to rate on a Likert scale of 1-6, from strongly disagree to strongly agree, how strongly they felt about returning a research result to a participant given various scenarios and categories of results. Participants were also asked for their opinions on the process of returning research results including: the informed consent process, timing of disclosure, and individuals to be consulted before the return of a result.

Counselors who had prior experience with IRR disclosure were directed to additional questions which assessed whether they had actually returned specific types of research results in the specific scenarios given (the scenarios and types of results were similar to those found in the 'opinion' section of the survey.) These participants were also asked about the actual process of returning research results utilized in their practice.

Data Analysis

Survey responses were analyzed using the Statistical Package for the Social Sciences (SPSS Inc.) version 19.0, and frequencies of responses for quantitative questions were calculated. Counselors were asked how often they encounter or disclose research results in their practice and for analyses, these frequencies were recoded and stratified into two groups: those who never encounter IRRs (ie: no experience with research results) and those who at least sometimes encounter research results (ie: at least some experience with IRRs).

Statistical comparisons between practice characteristics (years of experience, type of counselor and geographical region) were performed using bivariate statistical tests including independent sample T-test, one-way ANOVA (analysis of variance) and Pearson's correlation. To test differences in counselors' opinions across different scenarios and types of research results, a repeated measures ANOVA with 2 within-subject factors was also performed. Open ended questions were used to supplement the discussion.

Results

Demographics

Of the approximately 2,500 genetic counselor members of NSGC who received the recruitment notice, 260 respondents participated in the survey. Counselors who answered fewer than three questions were not included in data analysis. After these exclusions, 163 surveys were included in the data analysis, resulting in a response rate of 6.52%. Table I summarizes the demographics of study participants. Most participants identified themselves as clinical counselors (55.3%). The largest groups of respondents were counselors who encountered research results less than once a month (45.7%), counselors from the Midwest (region 2, 27.9%), counselors who had been practicing for 6-10 years (29.8%) and counselors for whom the main area of practice was cancer genetics (19.2%).

Counselors were asked how often they encounter or disclose research results in their practice (Figure 1). Over forty-five percent of respondents encountered research results less than once a month in their practice, and only 1.2% of survey respondents encountered research results daily.

Table I. Demographic information of genetic counselor study participants

	Percent (%)	Frequency (n)	Total (N)
Clinical vs. non-clinical			150
Clinical	55.3	83	
Non-clinical	26.7	40	
Both	18.0	27	
Region*			147
1	17.7	26	
2	27.9	41	
3	26.5	39	
4	20.4	30	
5	7.5	11	
Years of Clinical Practice			141
<1-2 years	28.4	40	
3-5 years	17.0	24	
6-10 years	29.8	42	
11-15 years	10.6	15	
16-20 years	5.7	8	
>21 years	8.5	12	
Main area of practice			287**
Cancer genetics	19.2	55	
Pediatric	12.5	36	
Adult	11.5	33	
Research	10.5	30	
Prenatal	10.5	30	
Specialty Disease	8.7	25	
Genetic Testing	5.2	15	
Other	4.9	14	
Education	4.2	12	
Population/biobanking	3.1	9	
Laboratory	2.8	8	
Genomic Medicine	2.8	8	
Public Health	2.1	6	
Administration	1.0	3	
Public Policy	1.0	3	

*Region 1=CT,ME,MA,NH,RI, VT,NJ,NY,PA; Region 2= IA,IL,MI,OH,WI,IA,KS,MN,MO,NE,ND SD; Region 3=DE,DC,FL,GA,MD,NC,SC,VA,WV,AL,KY,MS,TN,AR,LA,OK,TX; Region 4=CA,AZ,NV,UT,NM,CO,WY,MT,ID,OR,WA; Region 5= outside of Continental US

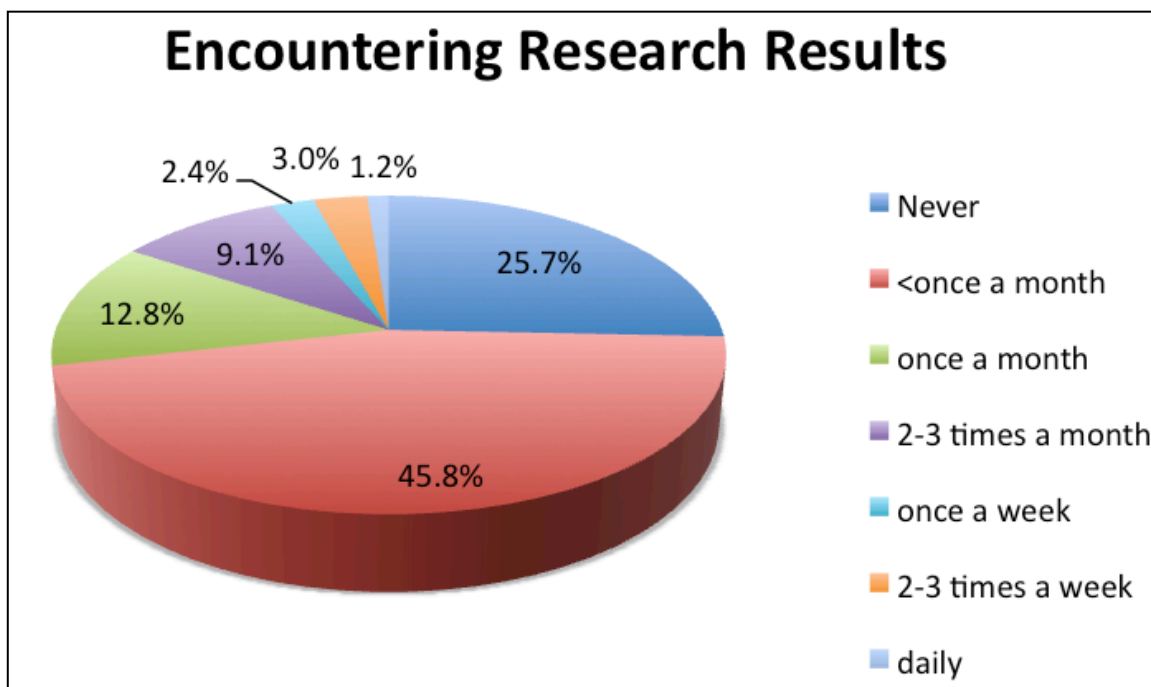


Figure 1. Percentages of genetic counselors who encounter Individual Research Results (IRRs) at various frequencies.

The sampled population was not representative of the general genetic counselor population as reported in the 2010 NSGC Professional Status Survey. The groups were significantly different ($X^2(5)=26.761, p<.0005$) by years of experience, with an over-representation of genetic counselors with more years of experience and an under-representation of counselors with 0-4 years of experience in the study population. There was no significant difference ($X^2(5)=8.686, p<.122$) by geographic region between this study's sample and the genetic counselor population as reported in the professional status survey.

Opinions regarding returning research results

When assessing opinions on IRR disclosure in general, responses indicated that counselors agreed more often than not on their desire to return IRRs (Figure 2).

However, counselors tended to disagree that giving research participants information about their own health or reproductive considerations was more important than keeping research results and clinical results separate ($F(2.574)=39.517, p<.0005$).

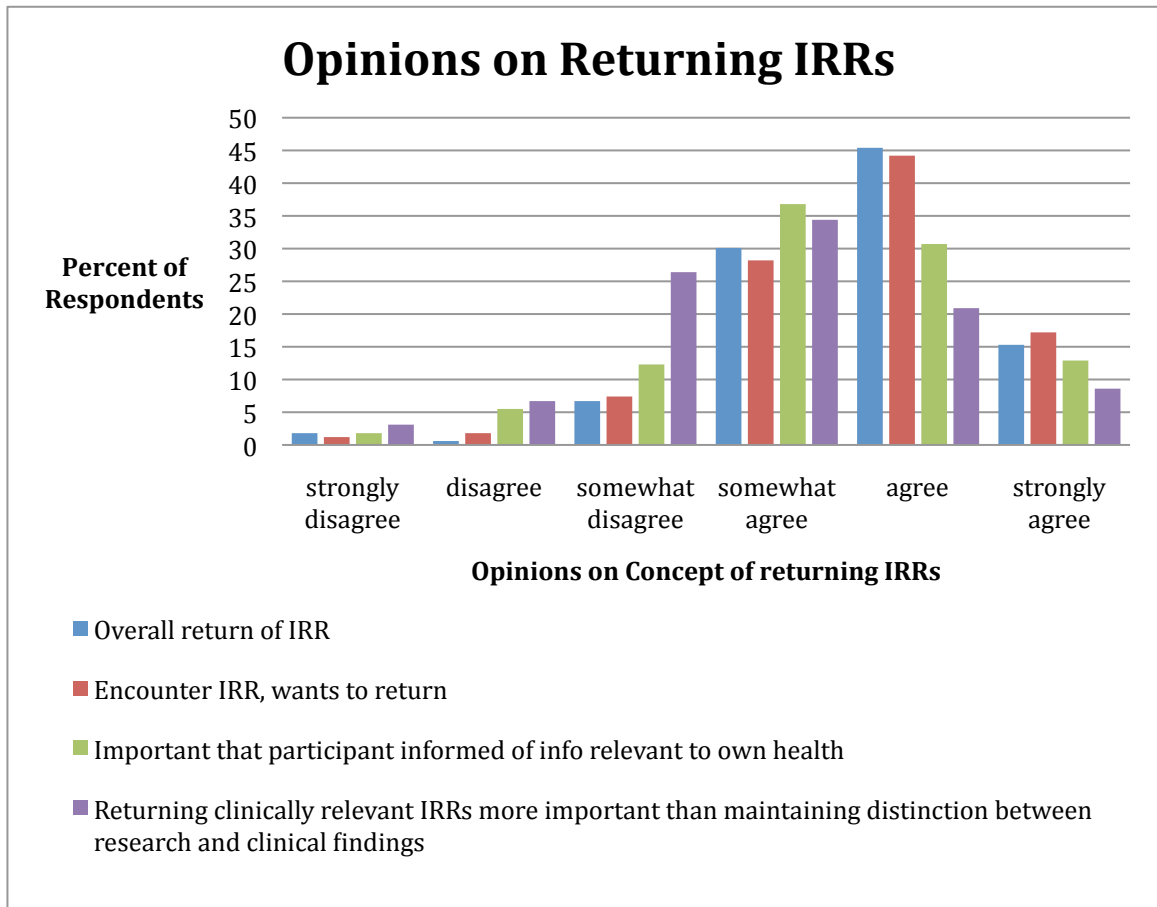


Figure 2: Counselor opinions on returning IRRs

Significant differences were found between counselors who never encountered IRRs and those who at least sometimes encountered IRRs on two questions. Counselors who encountered IRRs agreed (91.8% agreed) more often than counselors who never encountered IRRs (88.1% agreed) that IRRs should be returned to participants ($t(164)=-3.156, p=0.002$). Counselors with IRR experience

also agreed slightly more (90.1% agreed) than counselors without such experience (88.1%) that if they were to encounter an IRR, they would want to disclose the result ($t(164)=-2.089, p=.038$).

There was a significant effect of practice region on the responses to the question 'If I were to encounter an IRR, I would want to give that information to the research participant' [$F(4,142)=3.508, p=.009$]. The mean score for region 5 ($M=4, SD=.894$) was significantly lower than the mean score for region 3 ($M=5.05, SD=.724$). However, on all of the four questions asking about overall opinions, in all other conditions, there were no significant differences on responses by geographical region.

Opinions on returning different types of IRRs in various scenarios

Analyses of the effect of scenario, and type of research result on responses noted a significant effect between each scenario ($F(2.360)=252.808, p=.000$), between each type of research result ($F(3.771)=169.394, p=.000$) and between both scenario and result type ($F(9.144)=13.956, p=.000$). Participants were most in favor of returning clinically actionable results, reproductive results, and presymptomatic results. Participants felt the strongest that results should be disclosed in the scenario in which an adult participant gave informed consent ahead of time, followed by the scenario in which the result pertains to a child (or legal minor) and consent was given, followed by the scenario in which the result pertained to an adult but no consent was given ahead of time (or it wasn't included on the consent form), and then lastly, the scenario in which the result pertained to a child (or legal minor), but no consent was given.

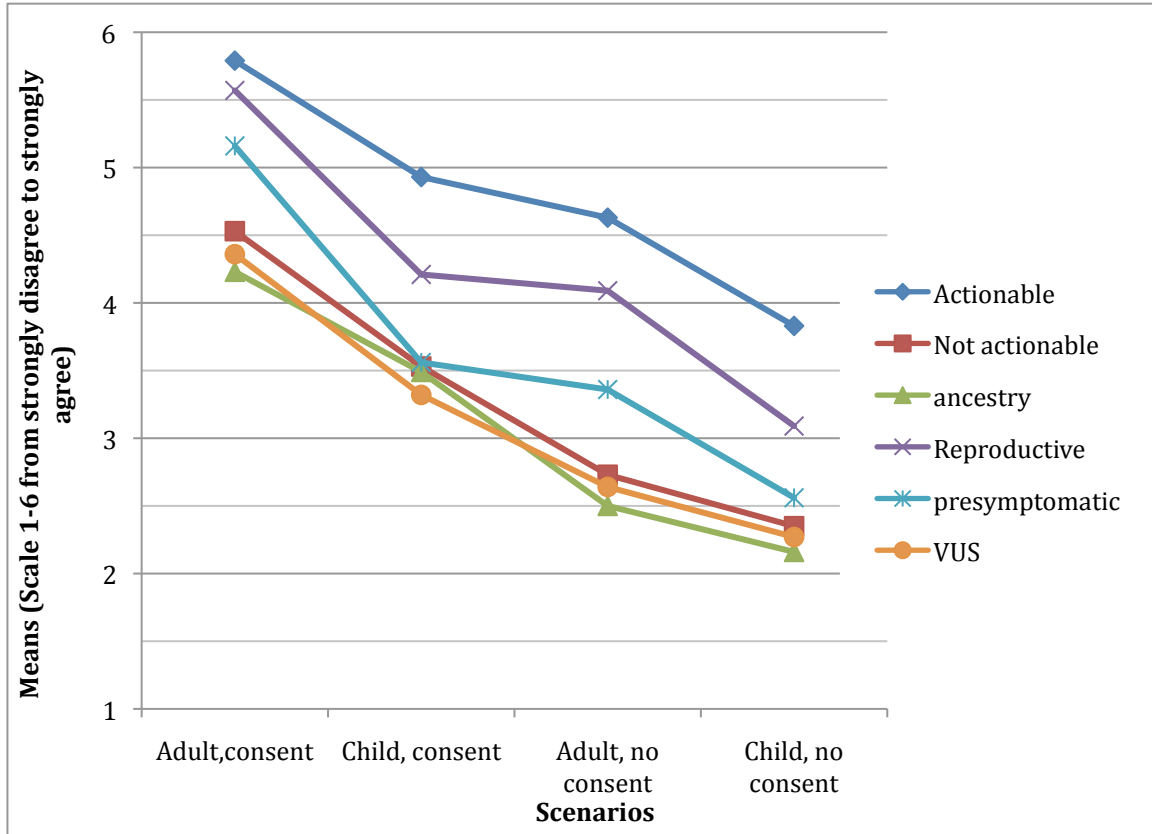


Figure 3: Average participant opinions by scenario and type of result.

There were no significant differences on scenario questions between counselors with IRR experience and counselors without.

Counselors with more years of experience were slightly more likely to agree that a reproductive result pertaining to a child (or legal minor) with consent should be disclosed than counselors with less experience ($r=.182$, $p=.027$). There were no other significant correlations between years of experience and scenario or type of result.

Opinions on the process of returning results

When asked what should be disclosed to participants before a result has been CLIA confirmed, 29.6% indicated no information should be given; 22.8%

advocated for full disclosure (including name of the disease, gene, and type of result) with the caveat that it needs to be CLIA confirmed; and 21.6% indicated the participant should be told that something was found, but details could not be provided before CLIA confirmation.

When prompted to choose one or more options for who the genetic counselor/researcher should consult with when deciding to return a research result, respondents indicated the study PI (50.4%), followed by the IRB (44.2%), colleagues (40.4%) and an independent oversight board (ICOB) (35.4%). A fraction of a percent (.8%) of respondents indicated that outside consultation was not needed. (totals sum to more than 100% because respondents could choose more than one option). No statistically significant differences were identified in questions related to opinions on the results disclosure process between counselors who previously encountered IRRs and counselors who did not.

Participants were asked to briefly describe their ideal informed consent process of a genetic research study with the possibility of IRR disclosure. Several common themes were identified, including: 1) giving participants the option to learn about different types of results, 2) researchers deciding ahead of time which results would be returned, 3) importance of clarity before consent is signed and participants are enrolled, 4) importance of genetic counseling and 5) importance of CLIA confirmation. One counselor wrote,

“I think it should be clear in the enrollment paperwork as to what results will be provided and patients should have the option to receive or not receive results. It should also be clear that a genetic counselor should provide the results to a family or someone else appropriately trained.”

Experiences with returning various results

For each scenario and type of result, counselors who encountered IRRs had significantly more agreement between opinions and experiences, than disagreement. Counselors with more years of experience were slightly more likely to agree that a presymptomatic result pertaining to a child (or legal minor) with no consent ahead of time should be disclosed than counselors with less experience ($r=.357$, $p=.038$). There were no other significant correlations between years of experience and scenario or type of result.

Experiences with the process of returning results

Figure 4 demonstrates responses to what specifically is disclosed to research participants prior to CLIA confirmation. Over 31% of respondents indicated that they have disclosed all of the information including the name of the disease/gene or finding and its clinical relevance with the caveat that the result needed to be confirmed in a CLIA certified laboratory. When prompted to choose one or more options for what is actually done when deciding whether to return a particular research result, 63.9% indicated they consult with the PI of the study, 49.2% consulted with colleagues, 41% consulted the IRB, 14.8% consulted with an independent oversight and 4.9% made the disclosure decision without consultation.

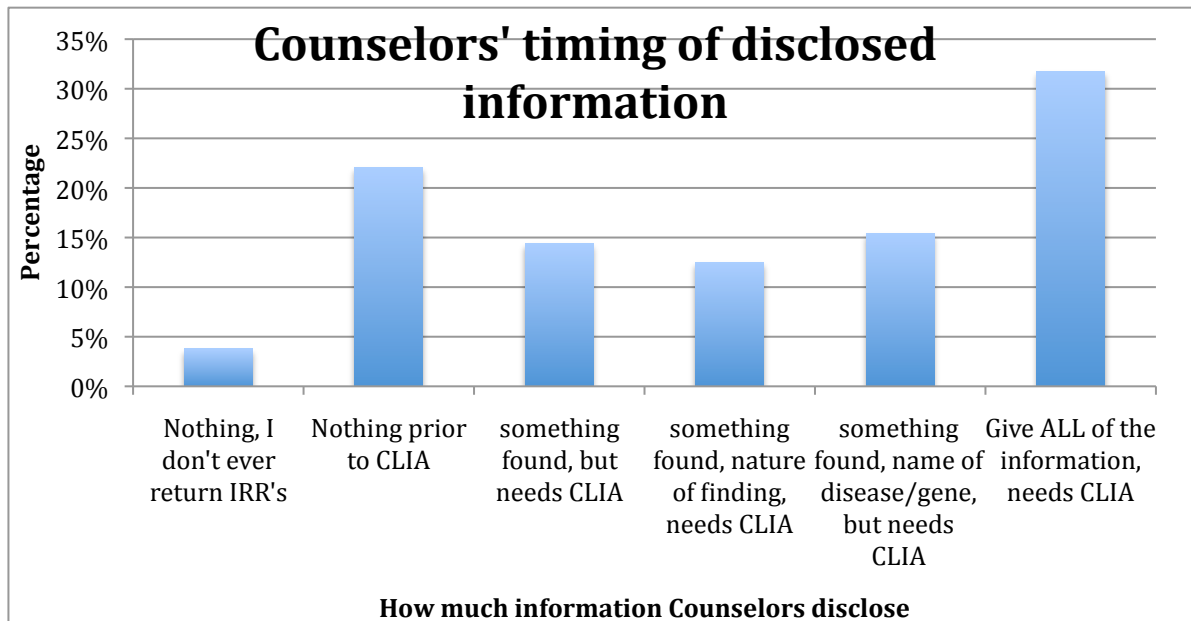


Figure 4: Information given to participants prior to CLIA confirmation

Several prominent themes were identified when respondents were asked to describe their actual process for returning an IRR including: 1) consultation with the IRB, 2) consultation with the PI, 3) determination of the result’s clinical significance, 4) importance of informed consent, 5) importance of CLIA certification, 6) importance of genetic counseling or consultation with an appropriate expert for the participant, 7) involvement of a physician and 8) discomfort/frustration with the current protocol for handling IRRs. As one counselor noted:

“This issue is a major problem in my department and we do not have a simple protocol for returning IRRs. Generally, we assist with confirming any research findings if patients or their doctors ask about what has been found in the research lab. I find this approach problematic and unequitable, however I do my best to handle each case as well as I can because often investigators who are not trained in genetics and who do not understand the importance of CLIA certification disclose results from databases anyways. I am working to improve this situation. As an aside, I have not found the IRB to be helpful and in fact find that they often complicate matters and propose overly complicated, non-sensical solutions dealing with issues related to genetic research.”

Another counselor reports experience based on a specific research protocol and IRB:

“Our IRB protocol allows us to return IRR when they are clinical significant. We are permitted to send them a letter stating that a result has been identified and if they choose to learn more about they result, please contact us. We then discuss clinical confirmation process and coordinate that testing at the patient's expense. We do not report negative results or VUSs.”

Consideration of the participant’s consent as well as the importance of CLIA

confirmation were noted by another counselor:

“Participants tell us what kinds of results they would like to receive. We CLIA validate and return results they want and don't CLIA validate and therefore, do not return, results they don't want. We do not CLIA-validate research results that are not desired by research participants UNLESS the result has potentially life-saving implications (BRCA1/2 mutation, etc.). We never return non-CLIA-validated results.”

Discussion

The purpose of this study was to assess the opinions and experiences of genetic counselors with respect to returning Individual Research Results (IRRs). Their input is important since genetic counselors are frequently the professionals who serve as patient liaisons, by interpreting information, consenting research participants, returning IRRs and representing both participants' and researchers' best interests.

Attitude on returning research results

Genetic counselors agreed that IRRs should be returned, and in practice, they would want to disclose IRRs to research participants. However, respondents indicated that keeping research and clinical results separate was a more important factor than blindly ensuring return of IRRs. Indeed, a recurring theme in this study was the need to carefully tread the line between research and clinical results, and to try to keep them separate. This is evidenced by counselors emphasizing the need to confirm a result in a CLIA certified laboratory before disclosure. This is also a common opinion expressed amongst researchers who have questioned whether the role of patient and participant could become clouded, potentially leading to suboptimal patient care due to disclosure of research information that may not be analytically valid (Henderson et. al, 2007). It is therefore unsurprising that counselors who are trained in patient advocacy and to place priority on a patient's

interests (NSGC,1992) indicated the need to CLIA confirm research results thereby assuring accuracy and validity.

Counselors with experience returning IRRs were slightly more likely to agree that IRRs should be returned to research participants compared to respondents who did not have experience returning IRRs, suggesting that counselors who encounter IRRs might be more comfortable handling such findings due to experience. This is also consistent with researchers' desire to return IRRs (Meacham, et al., 2010).

Disclosing various IRRs in different situations

We hypothesized that counselors would feel differently about disclosing various types of IRR. Indeed we found that counselors' opinions varied significantly by type of result and scenario. In particular, counselors agreed most strongly with returning clinically actionable results, followed by reproductive results (which are actionable), presymptomatic results (also arguably actionable) and lastly, results that were not actionable, results regarding ancestry and VUS's. This may partly be explained by the concept of 'partial entrustment'. Richardson & Belsky (2004), which describes the researcher- participant relationship as one of 'partial entrustment' in which researchers are given certain discretionary rights over the health and wellbeing of participants, and therefore are to a certain extent, trusted to refer for ancillary care. Under this concept, it is reasonable to deduce that a researcher would have a duty to disclose a clinically actionable result for which care and action could potentially be taken to possibly save a life. However, one could argue, that 'partial entrustment' has limits and that a researcher would not have the

duty to disclose any non-actionable or questionably actionable result. Counselors' opinions were consistent with the concept of 'partial entrustment' as they felt more strongly about returning results for which action could be taken or ancillary care was available.

Similarly, by scenario, participants tended to favor disclosure in scenarios in which informed consent was given prior to disclosure, and were also more likely to disclose a result pertaining to an adult compared to a child (or legal minor). This is in concordance with research ethics literature and genetic counseling practices which emphasize the need for informed consent as well as caution when conducting genetic testing in a minor, unless clinically necessary, or when symptoms are already present (Borry, Stultiens, Nys, Cassiman, & Dierickx, 2006). The legal inability of a minor to provide informed consent and the potential inability to provide assent has been documented and many genetic tests provide information actionable only in adulthood (Wertz, Fanos, & Reilly, 1994). Therefore, many genetic professionals hesitate to disclose genetic results pertaining to a child or minor, even when parental consent has been given.

Counselors' opinions about the process of returning IRRs

A complicated component of returning IRRs to research participants is the actual process. In practice, counselors may struggle with how much information should be disclosed to participants before CLIA confirmation. This study illustrated that counselors were nearly evenly divided on the subject. Some counselors thought that all information should be disclosed to participants prior to CLIA confirmation, some thought that no information should be disclosed, and others suggested

different iterations of disclosure in between the all or none options. Counselors were also divided about who to consult with regarding the decision of whether an IRR should be returned, although many indicated that the PI of the study should be consulted. However, in reality, the result would likely have been reviewed by the PI or other senior study staff before it was received by the counselor. Nevertheless, these varied opinions are not entirely unexpected given that a consensus still does not exist in the wider research community regarding IRR disclosure. Unfortunately, as opinions amongst counselors varied so widely, it is hard to form recommendations about the process based solely on the opinions expressed in this study. However, this study shows that counselors have valuable input about the process and should be consulted when guidelines are being established.

Counselors' experiences with returning research results

Interestingly, counselors who encountered IRRs, did not significantly vary on their opinions and experiences with returning IRRs amongst themselves. According to Fishbein & Aizen's 'Theory of Reasoned Action', a person's behavior depends largely on their attitude about such behavior (Fishbein, 1975). Therefore, one would not expect opinions and experiences to be different since generally, people's opinions inform their actions. One might expect these to vary if counselors had to follow certain institutional policies which conflicted with their own opinions. However, this did not appear to be the case in this present study.

A small but significant correlation of years of experience and responses was found for the scenario in which a presymptomatic result pertains to a child (or legal minor) and no consent was given ahead of time. Counselors with more years of

experience were slightly more inclined to disclose this type of result. This may be because counselors with more years of practice have seen the possible benefits of disclosing presymptomatic results regarding a child and may have faced losing individuals and families to followup and possibly losing an opportunity to share important medical information. Another possible explanation is that counselors are merely following institutional policies and that years of experience is not a true differentiating factor.

Experience with the process of returning IRRs

Like opinions, on the issue, counselors' real-life experiences vary significantly with regard to how much is disclosed to the participant before CLIA confirmation. Again, a common response to who is consulted when deciding to return an IRR, was the PI of a study, although there remained significant variation among the responses to this question. These results suggest that there is inconsistency in the current process of returning IRRs. In fact, counselors' responses to open-ended questions expressed frustration with this lack of consensus suggesting the need for consistent guidelines to not only streamline the process but also alleviate some of the process difficulties and ethical and legal complications which genetic counselors encounter.

Limitations

This study was designed to compare responses from genetic counselors with IRR experience to those without such experience. A limitation of this study was the stratification of counselors who encountered IRRs and counselors who did not. It may have also been informative to differentiate between counselors who would self-

identify as primarily a 'clinical counselor' versus those who would self-identify primarily as a 'research counselor'. Our study allowed respondents to select a 'both clinical and non-clinical' option, thus making it difficult to establish clear distinctions by practice-type in this current study. Although clinical and research counselors may both have encountered IRRs, their work experience may have shaded their experience differently. Clinical genetic counselors regularly order genetic testing from CLIA certified laboratories, handle clinical results disclosure and meet with patients to counsel and discuss implications of testing and likely have much less experience with pure research results. On the other hand, research genetic counselors usually do not routinely counsel patients or order testing from a CLIA certified laboratory but likely have more familiarity with handling research findings.

Although all genetic counselors were invited to participate, since the subject of the survey was returning research results, there may have been a response bias for counselors who currently encounter and/or disclose research results. However, there were few statistically significant differences between counselors who encountered IRRs and those who do not. Similarly, this study included significantly more counselors with six or more years of experience compared to newly practicing counselors. A larger study sample with more counselors from every category may have more accurately depicted opinions and experiences of the genetic counseling community as a whole. That said, there was no significant correlation between years of experience and responses to the majority of survey questions.

Conclusion

This study aims to assess the opinions and experiences of genetic counselors regarding the return of Individual Research Results (IRRs). Although there has been significant thought and debate in the research community on this topic, this is the first study to report the genetic counselor perspective. It illustrates that there is a general consensus among counselors in favor of returning clinically actionable research results. Nonetheless, there is significant variation in the prescribed process of deciding to return IRRs, and the actual disclosure procedure which will require additional study and evaluation. This study is an important stepping stone in establishing guidelines for the return of IRRs with contributions from the genetic counselor community.

Appendix A: Recruitment Notice

Subject line: Request for participation: a Study on the Return of Individual Research Results

Title:

Return of Individual Research Results: A survey of Genetic Counselors' Opinions and Experiences

Do you have experience with or an opinion about returning individual research results (IRR's) to study participants?

I am a graduate student in the Genetic Counseling Program at Brandeis University and I am seeking volunteers to participate in a research project.

What is the purpose of the study?

The goals of this project are to:

1. Assess genetic counselors' experiences in returning IRRs
2. Establish a consensus of opinions among genetic counselors regarding the return of IRR's.

Who can participate?

Participation is open to all genetic counselors working in research, clinical or other settings.

What does study participation involve?

Participation involves completing an online, anonymous survey which should take approximately 20 minutes of your time. All participants who complete the survey will have the opportunity to enter a raffle to win a \$50 gift certificate to amazon.com.

If you are interested in participating, please follow this link for additional details and to enter the online survey:

https://brandeis.qualtrics.com/SE/?SID=SV_bxqO3cwMutt21y4

I appreciate your willingness to participate in this study and look forward to hearing from you. Please contact me by email at dmsinger@brandeis.edu if you have any questions or comments or would like more information.

Sincerely,

Danielle Singer
Genetic Counseling Graduate Student
Brandeis University
Waltham, MA

Appendix B: Survey Instrument

Q1 Thank you for participating in this study.

This study is entitled: 'Return of Individual Research Results: A Survey of Genetic Counselors' Opinions and Experiences.' In this study you will be asked questions about your opinions and experiences with the return of research results. All information will remain anonymous. At the end of the survey, you will be asked for your email address to be entered to win one of two gift certificates. Your email address will NOT be linked to your survey responses and will be kept completely confidential. All information will be analyzed with answers from other participants. Please note that participation is voluntary and you may exit the survey at any time. By clicking next you have acknowledged that you have read the above information and that you wish to participate in the survey.

This study has been reviewed and approved by the Institutional Review Board of Brandeis University. If you have any questions about your rights as a research subject, please contact the Brandeis Institutional Review Board at irb@brandeis.edu or (781)736- 8133. If you have any questions about this study, please contact: Danielle Singer, Brandeis University Genetic Counseling Master's candidate 2012 at dmsinger@brandeis.edu or (240)506-4358.

Q2 For the purposes of this survey the following terms are defined. You may have heard other definitions for these terms. However, for the purposes of this survey please employ the following definitions:

- 1) '**Individual Reseach Result' (IRR):** "A finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research." (Wolf, 2008) IRR's can be BOTH within the aims of a research study AND beyond the aims of a research study.
- 2) '**CLIA certified laboratory**': A laboratory which meets with the standards of the 'Clinical Laboratory Improvement Amendments' and is legally certified by CMS to conduct clinical testing or any testing which is returned to a patient.
- 3) '**Clinically actionable result**': "A finding for which there are established therapeutic or preventative interventions or other available actions that have the potential to change the clinical course of the disease." (Fabsitz, 2010) For example, an established pathogenic mutation in the BRCA gene which predisposes an individual to Breast Cancer.
- 4) '**A finding with reproductive significance**': A finding which could be an important factor in any reproductive decision making. For example, carrier status for a particular disease like Cystic Fibrosis.
- 5) '**Presymptomatic finding**': A finding which confers a significant risk for an individual to develop a specific disease but for which they currently have no

symptoms. For example, a mutation which indicates that an individual will develop Huntington's disease.

6) '**Ancestral information**': A finding which provides information about an individual's ancestry. Such as non-paternity or country of origin.

7) '**Variant of uncertain significance**': A genetic finding which has not been previously described in the literature, and which may or may not be pathogenic

Q3 In your work, how often do you encounter/disclose Individual Research Results (IRR's)?

- Never (1)
- Less than Once a Month (2)
- Once a Month (3)
- 2-3 Times a Month (4)
- Once a Week (5)
- 2-3 Times a Week (6)
- Daily (7)

Q4 The initial set of questions ask for your opinions and beliefs about returning research results. Please answer the following questions based on your own opinions as best you can, REGARDLESS OF CURRENT PRACTICES!

Remember, these are the definitions you should employ when answering questions:

1) '**Individual Reseach Result' (IRR):** "A finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research."(Wolf, 2008) IRR's can be BOTH within the aims of a research study AND beyond the aims of a research study.

2)'**CLIA certified laboratory**': A laboratory which meets with the standards of the 'Clinical Laboratory Improvement Amendments' and is legally certified by CMS to conduct clinical testing or any testing which is returned to a patient.

3)'**Clinically actionable result**': "A finding for which there are established therapeutic or preventative interventions or other available actions that have the potential to change the clinical course of the disease." (Fabsitz, 2010) For example, an established pathogenic mutation in the BRCA gene which predisposes an individual to Breast Cancer.

4)' **A finding with reproductive significance**": A finding which could be an important factor in any reproductive decision making. For example, carrier status for a particular disease like Cystic Fibrosis.

5)'**Presymptomatic finding**': A finding which confers a significant risk for an individual to develop a specific disease but for which they currently have no symptoms. For example, a mutation which indicates that an individual will develop Huntington's disease.

6) '**Ancestral information**': A finding which provides information about an individual's ancestry. Such as non-paternity or country of origin.

7)'**Variant of uncertain significance**': A genetic finding which has not been previously described in the literature, and which may or may not be pathogenic

Q5 Please rate the following statements from strongly disagree to strongly agree on how you feel overall about the general return of research results

	Strongly Disagree (1)	Disagree (2)	Somewhat Disagree (3)	Somewhat Agree (4)	Agree (5)	Strongly Agree (6)
Individual	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<p>research results (IRR) should be returned to research participants (1)</p> <p>If I were to encounter an IRR, I would want to give that information to the research participant (2)</p> <p>It is really important that research participants are informed of any information produced from the research pertaining to themselves (3)</p> <p>Giving research participants information about their own health or reproductive considerations is more important than keeping research results and clinical results separate (4)</p>	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○

Q6 The following types of results should be returned to a research participant.

Please rate how you would feel about this statement in each of the following situations. Assume that participants gave INFORMED CONSENT to receive such a result, and the result has been confirmed in a CLIA CERTIFIED LABORATORY.

	Strongly Disagree (1)	Disagree (2)	Somewhat Disagree (3)	Somewhat Agree (4)	Agree (5)	Strongly Agree (6)
A research result which is clinically actionable (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is NOT clinically actionable (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information about ancestry (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information of reproductive importance (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result for a presymptomatic individual (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is a Variant of Uncertain Significance (VUS) (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q7 The following types of results should be returned to a research participant.

Please rate how you would feel about this statement in each of the following situations. Assume that participants were NOT specifically consented to receive such a result, (or it was NOT included on the consent form) and the result has been confirmed in a CLIA CERTIFIED LABORATORY.

	Strongly Disagree (1)	Disagree (2)	Somewhat Disagree (3)	Somewhat Agree (4)	Agree (5)	Strongly Agree (6)
A research result which is clinically actionable (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is NOT clinically actionable (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information about ancestry (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information of reproductive importance (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information for a pre-symptomatic individual (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is a VUS (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q8 The following types of results should be returned to a research participant.

Please rate how you would feel about this statement in each of the following situations. Assume that the participant is a CHILD OR LEGAL MINOR, the legal guardian gave INFORMED CONSENT to receive such a result and the result has been confirmed in a CLIA CERTIFIED LABORATORY.

	Strongly Disagree (1)	Disagree (2)	Somewhat Disagree (3)	Somewhat Agree (4)	Agree (5)	Strongly Agree (6)
A research result which is clinically actionable in adulthood (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is NOT clinically actionable (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information about ancestry (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information of reproductive importance (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information for a pre-symptomatic individual (for an adult-onset condition) (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

result which is a VUS (6)						
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Q9 The following types of results should be returned to a research participant.

Please rate how you would feel about this statement in each of the following situations. Assume that the participant is a CHILD OR LEGAL MINOR, the legal guardian was NOT specifically consented to receive such a result (or it was NOT included on the consent form) and the result has been confirmed in a CLIA CERTIFIED LABORATORY.

	Strongly Disagree (1)	Disagree (2)	Somewhat Disagree (3)	Somewhat Agree (4)	Agree (5)	Strongly Agree (6)
A research result which is clinically actionable in adulthood (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is NOT clinically actionable (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information about ancestry (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information of reproductive importance (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information for a pre-symptomatic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

individual (for an adult-onset condition) (5) A research result which is a VUS (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Q10 Once it has been decided to return a result to a participant, how much do you think should be disclosed to a participant AFTER the investigators find a variant, but BEFORE the finding has been certified in a CLIA laboratory?

- Nothing, I just don't think research results should ever be returned to participants under any conditions (1)
- Nothing prior to the result being CLIA certified (2)
- Something was found, but before providing participant with details it needs to be CLIA certified (3)
- Something was found, the nature of the finding (what type of finding it is, whether it's clinically actionable, of reproductive significance) without actually disclosing the result and before providing participant with details, the finding needs to be CLIA certified (4)
- Something was found, the name of the disease/gene or finding, but before providing participant with more details it needs to be CLIA certified (5)
- Give participant ALL of the information, something was found, name of the disease/gene or finding it's clinical relevance etc... BUT with the caveat that this result needs to be CLIA certified (6)

Q11 Which of the following do you think SHOULD be done when a genetic counselor or researcher are deciding whether/how to return an IRR? (Please choose all the apply)

- Consult the IRB (1)
- Consult with an independent oversight board designated for exactly this purpose (2)
- Consult with the PI of the study (3)
- Consult with colleagues (4)
- Decide on your own without any consultation (5)
- Other (6) _____

Q12 There are many approaches one could take in the informed consent process of a genetic research study. For example, some studies provide the option to participants to learn of individual research results (IRR) of different types. Others may only provide an option for certain types of results (such as pathogenic results within the aim of the study), while others may not include the possibility of IRR's in the

informed consent process at all. Please BRIEFLY (2-3 sentences) outline a summary of your IDEAL informed consent process for a genetic research study with regard to IRR's.

**BRANCHING LOGIC INSERTED:
IF ANSWER TO QUESTION 3 IS NOT NEVER, THE FOLLOWING BLOCK OF QUESTIONS (Q13- Q22) WILL BE DISPLAYED. IF PARTICIPANT ANSWERS NEVER TO QUESTION 3, SURVEY WILL AUTOMATICALLY REDIRECT TO Q23.**

Q13 The following set of questions ask about your ACTUAL EXPERIENCES AND PRACTICES with regard to the return of research results. Please answer the following questions based on your experiences, REGARDLESS OF YOUR OPINIONS as best you can.

Q14 I return the following types of results to research participants.

Please rate your agreement with this statement in each of the following situations. Assume that participants gave INFORMED CONSENT to receive such a result, and the result has been confirmed in a CLIA CERTIFIED LABORATORY.

	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)	N/A because I don't encounter this situation in my research (5)
A research result which is clinically actionable (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is NOT clinically actionable (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

about ancestry (3)					
A research result providing information of reproductive significance (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information for a pre-symptomatic individual (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is a VUS (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q15 I return the following types of results to research participants.

Please rate your agreement with this statement in each of the following situations. Assume that participants were NOT specifically consented to receive such a result (or it was NOT included on the consent form), and the result has been confirmed in a CLIA CERTIFIED LABORATORY.

	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)	N/A because I don't encounter this situation in my research (5)
A research result which is clinically actionable (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is NOT clinically actionable (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information about ancestry (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information of reproductive significance (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information for a pre-symptomatic individual (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is a VUS (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q16 I return the following types of results to research participants.

Please rate your agreement with this statement in each of the following situations. Assume that the participant is a CHILD OR LEGAL MINOR, that the legal guardian GAVE INFORMED CONSENT to receive such a result, and the result has been confirmed in a CLIA CERTIFIED LABORATORY.

	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)	N/A because I don't encounter this situation in my research (5)
A research result which is clinically actionable (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is NOT clinically actionable (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information about ancestry (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information of reproductive significance (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information for a pre-symptomatic individual (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is a VUS (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q17 I return the following types of results to research participants.

Please rate your agreement with this statement in each of the following situations. Assume that the participant is a CHILD OR LEGAL MINOR, that the legal guardian was NOT specifically consented to receive such a result (or it was NOT included on the consent form), and the result has been confirmed in a CLIA CERTIFIED LABORATORY.

	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)	N/A because I don't encounter this situation in my research (5)
A research result which is clinically actionable (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is NOT clinically actionable (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information about ancestry (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information of reproductive significance (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result providing information for a pre-symptomatic individual (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A research result which is a VUS (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q18 Which of the following do you do when you are deciding whether to return an IRR? (Please choose all the apply)

- Consult the IRB (1)
- Consult with an independent oversight board designated for exactly this purpose (2)
- Consult with the PI of the study (3)
- Consult with colleagues (4)
- Decide on your own without any consultation (5)
- Other (6) _____

Q19 My institution or research study has a specific protocol for handling IRR's

- True (1)
- False (2)
- Unsure (3)

Q20 Once it has been decided to return a result to a participant, how much do you disclose to a participant AFTER the investigators find a variant, but BEFORE the finding has been certified in a CLIA laboratory?

- Nothing, even though I encounter IRR's, I never return results to participants (1)
- Nothing prior to the result being CLIA certified (2)
- Something was found, but before providing participant with details it needs to be CLIA certified (3)
- Something was found, the nature of the finding (what type of finding it is, whether it's clinically actionable, of reproductive significance) without actually disclosing the result and before providing participant with details, the finding needs to be CLIA certified (4)
- Something was found, the name of the disease/gene or finding, but before providing participant with more details it needs to be CLIA certified (5)
- I give participant ALL of the information, something was found, name of the disease/gene or finding it's clinical relevance etc... BUT with the caveat that this result needs to be CLIA certified (6)

Q21 Please use the slider to indicate of all of the times that you encounter each of the following IRR's, what percentage of the time do you actually return such a result?

- _____ A clinically actionable result, such as a predisposition to Breast Cancer (1)
- _____ A non-clinically actionable result such as a predisposition to Alzheimer's disease (2)
- _____ A result providing ancestral information, such as non-paternity (3)
- _____ A result of reproductive significance, such as carrier status (4)
- _____ A result pertaining to a child or legal minor (5)

Q22 There are many approaches one can take if an Individual research result (IRR) is found within the context of a research study. For example, some might consult an IRB for guidance, or ensure that the IRR is CLIA- certified. Some might return only certain results, some might return no results and some may return all IRR's. In the box below, please BRIEFLY describe the process that you undertake after finding an IRR; how it is decided whether the result should be returned and then how you actually return the IRR.

Q23 Would you classify yourself as primarily a clinical genetic counselor or non-clinical genetic counselor?

- I am primarily a clinical genetic counselor (1)
- I am primarily a non-clinical genetic counselor (2)
- I am both a clinical and non-clinical genetic counselor (3)

Q24 Approximately how much time at your job do you spend counseling patients and doing clinically related activities?

- All of my time is spent counseling patients/doing clinically related activities (1)
- Most of my time is spent counseling patients/doing clinically related activities (2)
- I spend about 50% of my time counseling patients/ doing clinically-related activities and 50% of my time doing other activities (3)
- Some of my time is spent counseling patients/doing clinically related activities (4)
- None of my time is spent counseling patients/doing clinically related activities (5)

Q25 What are your MAIN roles as a genetic counselor? (Please choose all that apply)

- Clinical (1)
- Research/study coordinator (2)
- Administrative (3)
- Clinical coordination (4)
- Management (5)
- Teaching/Education/Supervising students (6)
- Customer liaison (7)
- Lab Support (8)
- Grant Management (9)
- Other (10) _____
- None of the above, I am not a clinical counselor at all (11)

Q26 What are your MAIN areas of practice?(Please choose all that apply)

- Laboratory (1)
- Genetic Testing (2)
- Cancer Genetics (3)
- Education: Public or professional (4)
- Specialty disease (5)
- Public Health (6)
- Administration (7)
- Prenatal (8)
- Genomic medicine (9)
- Population based/ biobanking (10)
- Pediatric (11)
- Adult (12)
- Public Policy (13)
- Research (14)
- Other (15) _____
- None of the above, I am purely a clinical genetic counselor (16)

Q27 What year did you graduate from your genetic counseling Master's program?

Q28 How many years have you been a practicing genetic counselor?

Q29 In which state do you currently work?

- Alabama (1)
- Alaska (2)
- Arizona (3)
- Arkansas (4)
- California (5)
- Colorado (6)
- Connecticut (7)
- Delaware (8)
- District of Columbia (9)
- Florida (10)
- Georgia (11)
- Hawaii (12)
- Idaho (13)
- Illinois (14)
- Indiana (15)
- Iowa (16)
- Kansas (17)
- Kentucky (18)
- Louisiana (19)
- Maine (20)
- Maryland (21)

- Massachusetts (22)
- Michigan (23)
- Minnesota (24)
- Mississippi (25)
- Missouri (26)
- Montana (27)
- Nebraska (28)
- Nevada (29)
- New Hampshire (30)
- New Jersey (31)
- New Mexico (32)
- New York (33)
- North Carolina (34)
- North Dakota (35)
- Ohio (36)
- Oklahoma (37)
- Oregon (38)
- Pennsylvania (39)
- Rhode Island (40)
- South Carolina (41)
- South Dakota (42)
- Tennessee (43)
- Texas (44)
- Utah (45)
- Vermont (46)
- Virginia (47)
- Washington (48)
- West Virginia (49)
- Wisconsin (50)
- Wyoming (51)
- I do not live in the continental United States (52)

PARTICIPANTS AUTOMATICALLY REDIRECTED TO ANOTHER SURVEY LINK:

Info survey

Q1 If you'd like, please provide your email address below to be entered into a drawing to win one of two gift certificates to Amazon.com. Remember, your email address and personal information will be kept confidential and will in no way be connected to your survey responses.

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