REPORT

Research Advocacy Network
Advancing Patient-Focused Research

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Research Advocacy Network 2010 Survey of Advocates

Providing Results to Participants in Biospecimen Studies

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Introduction

If you provided a biospecimen for research purposes, would you want to know the results of your individual tests? Would you want these results only if they had health implications? Who would you want to provide you with these results – your doctor? A genetic counselor? Someone else?

Biospecimens are small samples of any bodily tissue, fluid, or other substance, such as urine, blood, saliva, tissue from tumors, or small bits of normal tissue. Such samples may be obtained from individuals—with their knowledge and consent—to study disease processes. In some cases, biospecimens of healthy tissue may be needed to determine why some people or tissues stay healthy and others don't. Still other studies may examine why some people respond to medications and others don't, to determine why certain cancers behave the way they do, or to help develop new treatments.

A variety of different types of information can be obtained from biospecimens. Depending on the goal of the research study, tests might be performed for proteins, genes, or other biological molecules. Other research may assess tissue or cell structure.

Overview of Advocate Survey

In order to better understand how advocates feel about receiving results obtained from biospecimens, Research Advocacy Network (RAN) conducted a survey in the summer of 2010. Surveys were sent to 100 advocates identified through their participation in RAN-sponsored training programs. Thirty-two surveys were completed and returned.

The survey consisted of 13 questions, 10 of which could be answered as "yes" or "no", with some having an additional option of "it depends." If respondents chose the latter option, they were asked to explain their responses in 400 words or less. Two additional questions dealt with who should explain the results and a final open-ended question asked respondents whether they would like to voice anything else on the topic.

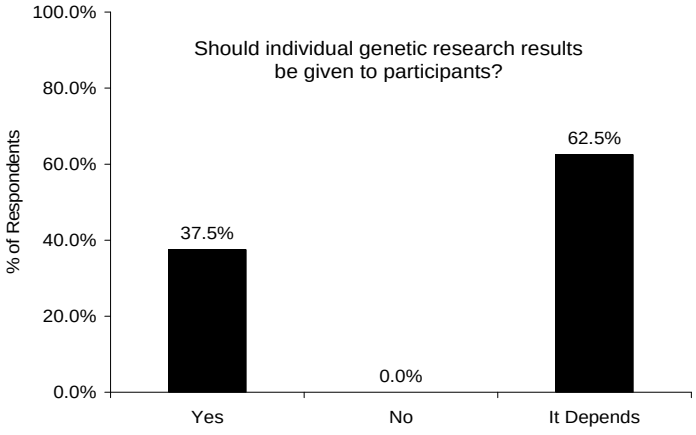
Survey Results

The first question in the survey was whether individual genetic research results should be given to study participants. As shown in the graph below, nearly two-thirds of respondents answered the question as "it depends", and no one said "no".

Many respondents noted that individual genetic results should be given to participants who request them. Others noted that the wish to receive individual genetic results would depend on full explanation in the consent form, the extent to which the results were clinically relevant and validated, the availability of a genetic counselor, and whether the patient is an adult or minor.

As a follow-up to the first question, respondents were asked who should provide the genetic results. Genetic counselor was the most popular option with 29%, followed by the "other" option (25%), physician (23%), the researcher (19%), and lastly the tissue bank staff member (3%). In the category of "other," respondents specified that the results should be provided by the person who was the most knowledgeable, the most qualified, and/or had a personal relationship with the participant.

A third question asked whether information on diagnostic discrepancies should be provided to



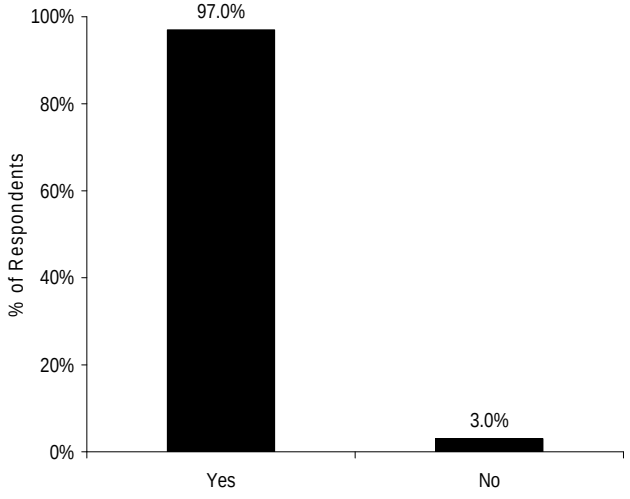
individuals who donated their tissue for research purposes. To this, slightly more than two-thirds (69%) answered "yes", 3% answered "no", and 28% answered "it depends". Among the latter group, respondents indicated that the answer depended on whether the discrepancies could be clarified, whether the test was approved by the government (Food and Drug Administration; FDA), and/or whether they impacted the health, welfare, or emotional well-being of the patient. One respondent noted that case-by-case discretion should be allowed for determining whether discrepancies should be provided.

More than three-quarters of respondents (78%) indicated that information about incidental findings should be provided to individuals who donated their tissue for research purposes. Nearly 20% answered "it depends" and 3% answered "no." For some, the answer to this question depended upon what was provided in the consent document, whether the patient elected to receive the information, the potential impact of the information on future medical care of the individual or their family, and/or whether the information related to a condition that could be prevented or treated more readily if detected early. One respondent indicated that letters could be send to individual participants recommending that they have a certain test performed by their physician's lab. Among those who answered "yes" to the incidental findings question, one-third indicated that the findings should only be provided if there were an intervention for the disease or condition identified, whereas two-thirds indicated that that disclosure of the findings should not be confined to diseases or conditions where interventions were available.

Nearly 70% of respondents indicated that they thought aggregate results from clinical studies using biospecimens should be provided to participants. Almost 30% answered "it depends" and 3% answered "no". For those who checked "it depends," most indicated that such results should be provided if the participant wanted them; others indicated that such information validates and respects participants. One respondent noted that this information might be overwhelming if the patient is still undergoing treatment.

In response to the question of whether individual results from clinical studies using biospecimens should be provided to participants, 34% said "yes", 16% said "no", and 50% indicated "it depends". Most of those in the latter group noted that individual results should be given if the person wants them. Others noted that individual results should be provided if they were likely to impact the health, welfare, or emotional well-being of patients; if the study were complete, un-blinded, and published; if others could benefit; if it were feasible; and/or if it were accompanied by an explanation from their doctor and genetic counselor. One respondent noted that "researchers should never be able to deduce information about an individual without sharing that information with the individual unless the individual has requested that such information not be shared."

As a follow-up question, the survey asked whether individual research results should be communicated *only* if they could have health implications for the participant and their families. Nearly two-thirds said "no" to this and just over one-third said "yes". A



subsequent question asked who should provide the individual results to the participant, with 38% indicating the physician, 28% indicating "other", 19% the researcher conducting the research, 16% the genetic counselor, and 0% the tissue bank staff. Among those who selected "other", several respondents indicated that more than one person should be involved in providing and discussing the results, including the physician, genetic counselor, and/or the researcher. Several respondents indicated that the most knowledgeable person should provide the results. Eighty-four percent of respondents indicated that the individual results should be analytically and clinically validated, and 16% disagreed.

The highest agreement in the survey centered on the question of whether the individual should be given an opportunity to decide whether they want to receive the research results. Nearly all respondents answered (97%) yes and only 3% answered no. Two-thirds of respondents indicated that patients should be required to receive counseling before and after receiving the research results, and 33% said disagreed.

Should the individual be given an opportunity to decide whether they want to receive the research results?

The last question of the survey asked whether respondents wanted to share anything else on the topic. Nineteen offered their thoughts and recommendations, which are summarized below.

- Research results should be provided to individuals who want them.
- Receiving research results encourages participation in future studies.
- Individuals should be kept updated on any finding in the study, good or bad.
- Research results should be transferred to the patient's chart.
- Research results that are incomplete or not validated and have no long-term health implications are likely to lead to anxiety.
- Clinical trials are group research studies and not individual treatment plans.
- Detailed explanations should be provided to study participants at each step.
- Informed consent can be used to address these issues.
- Physicians often do not have time to counsel patients, hence, the importance of a genetic counselor.
- Individuals providing the results should be well trained so that they can provide the information in a non-frightening way. Cultural competence education should be a component of this training.

Summary and Conclusions

Overall, the advocates who responded to the survey believe that participants in clinical studies should have the opportunity to receive the results of genetic or other tests performed on biospecimens collected as part of the trial. The respondents did not always agree on who should provide those results, whether information on diagnostic discrepancies and incidental findings should be provided, or whether genetic counseling should be required.

It must be noted that this survey was sent only to advocates who participated in RAN-sponsored training, and had a response rate of 32%. Thus, the results cannot be said to apply to the advocate population as a whole. However, the information revealed in this survey establishes a solid starting point for further dialog on providing research results to clinical study participants. Notably, the strong agreement (98%) that clinical trial participants should have the opportunity to receive their biospecimen test results indicates that this issue is important for researchers and advocates to address. The survey responses may serve as a guide to the concerns that should be taken into account in developing model programs.