Return of Genetic Research Results to Participants and Families: IRB Perspectives and Roles

Laura M. Beskow and P. Pearl O'Rourke

Whether or not to offer individual genetic results to research participants has been the subject of considerable debate, yet consensus regarding what, when, and how to return remains elusive.[1] Despite this lack of clarity, the discussion has moved to the offer of research results to family members of participants, including when the participant is deceased.[2] Given the familial implications of genetic information, this extension is perhaps logical. But it raises concerns throughout the research process, including, for example, questions about disclosures and choices on consent forms, procedures for identifying and contacting family members, and how any such obligations might apply to secondary users of biospecimens and data.

To date, there has been no study of Institutional Review Board (IRB) perspectives on these challenging issues. In addition, although some research has addressed IRB leaders' opinions on the general topic of return of results,[3] there has been little work regarding the role of the IRB in the development of guidelines, day-to-day implementation, and oversight of the process.

To help fill these gaps, we conducted an internet-based survey of IRB chairs and vice chairs at U.S. member institutions of the American Association of Medical Colleges (AAMC). Our aim was to investigate IRB leaders' perspectives on the return of individual genetic research results to participants and families, including family members of deceased participants, and on the proper role of the IRB in addressing these issues. Throughout this paper, the phrase "return of results" describes a process that begins with an *offer* to return research results.

Methods

Sample Assembly

Using AAMC's membership list, we searched the web sites of U.S. institutions to identify IRB chairs and vice chairs (hereafter referred to simply as "chairs"). When

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not available online, we obtained the information by contacting the institution directly. For those with multiple IRBs, we selected the chair of the biomedical IRB whenever possible; otherwise, we chose the chair of the first IRB listed. Survey communications to all prospective participants included the statement, "If you are an IRB chair but would prefer to recommend another chair at your institution who has more experience reviewing human genetic research, please let us know and we will direct our invitation to that person."

Instrument Development

We drafted our survey instrument based on our knowledge of the issues and literature concerning disclosure of individual genetic research results, informed consent, human research protections, and survey methodology. We revised the instrument based on iterative rounds of comments from colleagues with recognized expertise. Topics were organized in two main sections. The first focused on opinions about a hypothetical scenario in which researchers using a pancreatic cancer biobank discover a link to a gene called *CDKN2A* that may also increase risk of melanoma (Box 1).[4] The second gathered opinions about the proper role of the IRB in guideline development, decision making, and oversight of return of results processes.

The final instrument (see Online Supporting Information) consisted of 34 questions, primarily multiple choice and rating scale items, with all questions phrased around the "offer" of results. We expected the survey would take approximately 30 minutes to complete, and did not offer a monetary incentive for participation. The Duke University Health System IRB and the Partners' Human Research Committee deemed this study exempt under 45 CFR 46.101(b)(2).

Survey Implementation and Analysis

We implemented the survey on the web using Qualtrics survey software. The survey was fielded in March-May, 2013. We invited participants in three waves; if a first invitee did not complete the survey after two reminders, we conducted a second wave by inviting another chair from the same institution whenever possible. This process was repeated in a third wave. Responses were downloaded from Qualtrics for descriptive analysis using Microsoft Excel.

Results

Participant Characteristics

Of the 136 institutions invited, an IRB chair from 65 (48%) completed the survey. To assess this response rate, we conducted a brief literature search for publications reporting the results of online surveys of IRB chairs and/or members. Among the seven iden-

Box 1

Hypothetical Scenario*

As a recently-diagnosed pancreatic cancer patient, Pat volunteered to participate in a Biospecimen Resource for Pancreas Research at your institution. This research is not meant to provide care or treatment for Pat. Rather, researchers study blood samples and information collected from many people with the hope of making discoveries that will help cancer patients in the future.

Researchers analyzed all of the stored blood samples to look for genes that might be linked to pancreatic cancer. In the process, however, they made another discovery. Researchers found that people who have pancreatic cancer also sometimes have a mutation in a gene called *CDKN2A* that might result in an increased risk of developing melanoma.

> Here is more information about the implications of having a *CDKN2A* mutation: In one study (McWilliams 2011), researchers used data on first-degree relatives of pancreatic cancer patients who had a known *CDKN2A* mutation to estimate the associated risks. The cumulative risk of pancreatic cancer by age 80 in mutation carriers was estimated to be 58% [95%CI=8-86]; the risk of melanoma was 39% [95%CI=0-80]. The clinical utility of knowing whether one has a *CDKN2A* mutation has not been established. For example, there are no data documenting the efficacy of more frequent skin exams to reduce melanoma morbidity among mutation carriers; nor is there evidence of net benefit to offering pancreatic cancer screening to at-risk relatives, though some precancerous and cancerous lesions can be found.

Pat's sample is one of those that researchers found to have a mutation in *CDKN2A*. The consent form Pat signed at the time of enrollment in the Biospecimen Resource said the following:

> *"If a researcher finds that results obtained from the genetic research performed on your sample may be useful for your health care or your family members' health care, you may be contacted and given the choice to learn your results."*

*Adapted in part from other sources; see Acknowledgments

tified for which a response rate could be calculated,[5] rates ranged from 18-52% (mean=39%, median=44%). Two had response rates below 20%, three reported rates in the low- to mid-40%s, and two achieved rates in the low 50%s.

Most respondents were white, non-Hispanic males, age 50 or older, and had a medical background (Table 1). They reported, on average, 9 years' experience as an IRB chair and nearly three-fourths rated themselves as familiar or very familiar with the review of human genetic research protocols. Most, however, reported little involvement in the development and/or ongoing implementation of policies and procedures concerning the deposition of data into NIH's Database of Genotypes and Phenotypes (dbGaP). Over half said they would be generally interested or very interested in receiving genetic information about themselves.

Disclosure of Individual Genetic Research Results to Participants and Family Members

In response to the hypothetical pancreatic cancer biobank scenario (Box 1), in which the consent form included a statement that individual genetic results might be offered "if useful for your health care or your family members' health care," a large majority of respondents (77%) said Pat (the participant) should be contacted and offered her *CDKN2A* results. However, when asked if Pat's results should be offered to family members if Pat is deceased, only 25% said they should; most (58%) said they should not and 15% were unsure.

We asked a series of questions about the consent form described in the hypothetical scenario and invited respondents to consider how various alternative disclosures would affect their response in the situation where Pat is deceased:

- 51% said that if the consent form had been silent on the topic of return of results, this would have no effect on their opinion about whether Pat's results should be offered to family members.
- 55% said they would be *less* likely to favor disclosure if the consent form had said "Your individual genetic results will be given only to you."
- 77% said they would be *more* likely to favor disclosure if the consent form had said, "In the event we cannot contact you to offer research results, someone from the Biospecimen Resource may contact your representative or a family member."

Table 1

Participant Characteristics (n=65)

	n	(%)
Years as IRB chair/vice-chair: Mean = 9; range = 1-35		
Age		
<50 years	12	(18)
≥50 years	49	(75)
Sex		
Male	36	(55)
Female	26	(40)
Race §		
White	57	(88)
Asian	1	(2)
Black	2	(3)
Hispanic		
No	60	(92)
Yes	1	(2)
Professional background §		
Medicine / nursing	34	(52)
Social sciences	9	(14)
Epidemiology / public health	8	(12)
Bioethics	6	(9)
Genetics	5	(8)
Patient/participant/community perspectives	3	(5)
Law	1	(2)
Other	14	(22)
Type of IRB		
Biomedical	41	(63)
General	15	(23)
Social / behavioral	7	(11)
Other	2	(3)
Familiarity with review of human genetic research		
Not at all / not too familiar	4	(6)
Somewhat familiar	15	(23)
Familiar / very familiar	46	(71)
Involvement in development / implementation of dbGaP policies & procedures		
Not at all / not too involved	46	(71)
Somewhat involved	14	(22)
Involved / very involved	5	(8)
Interest in receiving genetic information about self		
Not at all / not too interested	13	(20)
Somewhat interested	14	(22)
Interested / very interested	35	(54)

Percentages may not sum to 100% due to missing data
§ Respondents were allowed to choose more than one

We further explored the topic of consent for the pancreatic cancer scenario by asking, "At the time participants consent to the Biospecimen Resource, should they be asked to make choices about receiving their own individual genetic research results?" Although a few respondents (11%) said no, approximately one-fourth (23%) said participants should be asked to make a yes/no choice, and over half (58%) said participants should be given a menu of options to choose the types of information they do and do not want to receive. With regard to whether participants should be asked to make choices about family members receiving the information:

- 22% said no, participants should not be asked to make such choices because family members should not be offered a participant's results (and thus no choices should be elicited);
- 11% said no, participants should simply be informed that their results may be offered to family members; and
- 62% said yes, participants should be informed that their results could be offered to family members and asked to indicate their choice(s).

We asked the latter group (n=40) about the kind of choice that should be solicited. A few (8%) said participants should be asked to make a yes/no choice; one-third (33%) said participants should be asked to designate one family member to serve as 'gatekeeper' (i.e., be responsible for sharing the results, at his/her discretion, with other family members); and over half (53%) said participants should be asked to designate all family members with whom they are and are not willing to have their information shared. When further queried about whether participants should be asked to obtain the permission of designated family members (i.e., confirm they wish to be offered the participant's individual genetic research results), the group was evenly split (45% yes; 48% no).

We then asked all respondents (n=65) to assume that Pat had been asked at the time she consented to the Pancreatic Cancer Biospecimen Resource whether she wanted family members to receive her results, and that Pat said "no." A substantial majority (88%) said that if Pat is now deceased, her decision should be followed and *CDKN2A* results not disclosed to family. The remaining minority was divided equally between those who felt her decision was no longer paramount and results could be disclosed (6%), and those who were unsure (6%).

With regard to the cost of disclosing genetic research results (e.g., confirmatory testing, genetic counseling), only 25% agreed with the following statement: "The Biospecimen Resource should offer individual *CDKN2A* results to participants and/or family members only if it has the funding to pay for costs associated with providing the information." Given the growing demands for large-scale sharing of research data,[6] we also asked how far an obligation to return results extends. Most (55%) answered "yes" to the question, "If the consent form indicated results would be offered if 'useful for your health care or your family members' health care,' should users of dbGaP be required to contact the Biospecimen Resource if they discover such information?"

We concluded this section of the survey by inquiring about a general population-based biobank (in contrast to the earlier one focused on patients diagnosed with a serious form of cancer) (Box 2). In this general, non-disease-specific context, half of respondents (51%) said "yes" when asked whether there are any circumstances in which family members should be offered a deceased participant's individual genetic research results. We queried these respondents (n=33) about how important various factors would be to their opinions on this subject (Table 2). A large majority said consent statements and the clinical validity of the results would be very important; most also considered clinical utility and the seriousness of the condition to be very important, while somewhat fewer assigned high importance to reproductive

Box 2

Description for Survey Questions about General Biobanks

Our questions up to this point referred to a specific scenario involving pancreatic cancer patients and a rare genetic result associated with increased risk for a serious form of skin cancer. For the remainder of the questions in this section, we would like you to consider a general biobank such as might be established at most any academic medical institution. Assume a biobank that does not focus on a particular disease, but rather collects blood and health information from patients and other volunteers regardless of their health history. The only requirements are that participants must be adults and able to give informed consent.

Table 2

Importance of Factors to Opinions about Whether Results Should Be Offered to the Family Members of a Deceased Participant in a General Biobank (n=33)

	Not at all important		Somewhat important		Very important	
	n	(%)	n	(%)	n	(%)
Statements in the consent form regarding whether or not individual genetic research results might be disclosed to family members	2	(6)	6	(18)	25	(76)
The level of **clinical validity** of the results (The accuracy with which the presence of a gene variant predicts the presence of a clinical condition or predisposition)	2	(6)	8	(24)	23	(70)
The level of **clinical utility** of the results (The availability and effectiveness of interventions aimed at avoiding the adverse clinical consequences of a gene variant)	3	(9)	8	(24)	21	(64)
The **reproductive implications** associated with the results (Results that may not affect the participants' health but suggest risk for disease among offspring, e.g., carrier status)	3	(9)	15	(45)	15	(45)
The **seriousness** of the condition associated the results (The level of morbidity and mortality expected if the person develops the condition associated with the gene variant)	2	(6)	13	(39)	18	(55)
Whether or not the results were generated (or confirmed) in a **CLIA-certified lab** (Standards that apply to labs that report patient-specific results "for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health")	3	(9)	18	(55)	12	(36)

Percentages may not sum to 100% due to missing data

implications and Clinical Laboratory Improvement Amendments (CLIA) certification.

The Role of the IRB in the Disclosure of Individual Genetic Research Results

In a second section of the survey, we queried respondents about what role the IRB *should* have with regard to offering results (as distinct from what IRBs may currently be doing). We asked them to assume throughout that there are at least some circumstances in which offering results to participants and/or family member may be appropriate.

POLICY EVELOPMENT

We posed a series of questions about the development of institutional policies or formal guidelines (herein referred to simply as "policy") concerning the disclosure of individual genetic research results. First, we asked about the development of policies that **define the general characteristics of individual results that should be offered** to participants. Although approximately one-third of respondents said the IRB should have ultimate authority to determine these policies, most said the IRB should provide input but not have ultimate authority, and a few said the IRB should not be involved (Table 3a). Among those in the latter groups, the most common answer about who should set such policy was a national entity, such as the federal Office of Human Research Protections (OHRP) or the National Institutes of Health (NIH) (Table 3b).

Second, we asked about developing policies that **define the circumstances under which family mem-**

Table 3a

Role of the IRB in Policy Development Concerning Disclosure of Individual Genetic Research Results (n=65)

	IRB should have:					
Policy Question	**Full authority**		**Input only**		**No role**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Defining the general characteristics of individual genetic results that **should be offered to participants** (Example: Results are analytically valid; have important health implications and associated risks are established and substantial; are clinically actionable; have reproductive implications)	22	(34)	33	(51)	5	(8)
Defining the circumstances under which **family members should be offered** a participant's individual genetic research results (Example: Only if participant consented to family disclosure; only if participant is deceased; only if results meet specific criteria)	25	(38)	32	(49)	4	(6)
Defining acceptable processes for **identifying and contacting family members** to offer a participant's individual genetic research result (Example: Who makes initial contact; initial contact by phone versus mail; family members asked to opt in versus opt out of learning more; availability of genetic counseling, referrals)	31	(48)	23	(35)	5	(8)
Defining the research **participant's role** in decisions regarding the process of offering genetic results to family members? (Example: Whether participants should be offered choices about family disclosure; weight given to participant choices; expectations of participant to contact family members with information about the study and possibility of disclosure)	36	(55)	21	(32)	3	(5)

Percentages may not sum to 100% due to missing data, as well as other answers not shown, which include "decisions should be made on a case-by-case basis (no policies developed)" and "unsure"

bers should be offered a participant's genetic results. Again, although over one-third of respondents said the IRB should have ultimate authority to determine such policy, about half said the IRB should provide input but not have ultimate authority, and a few said the IRB should not be involved (Table 3a). Among the latter groups, "a national entity" was most commonly identified as the proper authority (Table 3b).

Third, we asked about developing policies that **define acceptable processes for identifying and contacting family members** to offer a participant's genetic results. For this topic area, nearly half of respondents said that the IRB should have ultimate authority (Table 3a). Among the remainder, "another official/existing entity at my institution" was most commonly identified as the proper authority, although an equal proportion was unsure (Table 3b).

Fourth, we asked about developing policies that **define the research participant's role** in decisions regarding the process of offering genetic results to family members. Over half of respondents identified the IRB as having ultimate authority to determine such policy (Table 3a). Among the remainder, many were unsure who should have ultimate authority, although "a national entity" was a common response (Table 3b).

Considering Specific Results

We next asked respondents about the proper role of the IRB in real-time decision-making concerning the disclosure of a specific result, i.e., a result actually gen-

Table 3b

If Not the IRB, Who Should Have Authority for Policy Development Concerning Disclosure of Individual Genetic Research Results?

Policy Question	Existing institutional entity		Ad hoc institutional entity		National entity		Unsure	
	n	(%)	n	(%)	n	(%)	n	(%)
Defining the general characteristics of individual genetic results that **should be offered to participants** (n=38)	8	(21)	9	(24)	13	(34)	8	(21)
Defining the circumstances under which **family members should be offered** a participant's individual genetic research results (n=36)	8	(22)	9	(25)	11	(31)	8	(22)
Defining acceptable processes for **identifying and contacting family members** to offer a participant's individual genetic research result (n=28)	8	(29)	6	(21)	6	(21)	8	(29)
Defining the research **participant's role** in decisions regarding the process of offering genetic results to family members? (n=24)	5	(21)	4	(17)	7	(29)	8	(33)

Percentages may not sum to 100% due to missing data

Table 4a

Role of the IRB in Consideration of Specific Genetic Results (n=65)

	IRB should have:					
Consideration of Specific Results	**Full authority**		**Input only**		**No role**	
	n	(%)	n	(%)	n	(%)
Determining whether an actual genetic result **meets the criteria for disclosure** to participants and/or family members (Example: Whether the CDKN2A result found in the pancreatic research scenario should be offered)	30	(46)	21	(32)	10	(15)
Determining the **specific process** by which participants and/or family members are contacted and offered an actual genetic result (Example: Within the range of potentially acceptable approaches to family members, determining the specific process that should be used to contact and offer the CDKN2A result found in the pancreatic research)	36	(55)	22	(34)	4	(6)

Percentages may not sum to 100% due to missing data, as well as "unsure" answers not shown

erated in the course of a study (such as the *CDKN2A* result described in the Box 1). Although nearly half said the IRB should have ultimate authority to determine **whether an actual result meets the criteria** for disclosure to participants and/or family members (Table 4a), roughly the same proportion either said the IRB should provide input but not have ultimate authority or that the IRB should not be involved. Among the latter, "the researcher" was most commonly identified as the appropriate decision maker (Table 4b).

Over half of respondents said the IRB should have ultimate authority to determine **the specific process by which participants and/or family members are contacted** and offered an actual genetic result (e.g., within the range of potentially acceptable approaches laid out by policy) (Table 4a). Among the remainder, "the researcher" was again most commonly identified as the appropriate decision maker (Table 4b).

OVERSIGHT

With regard to oversight of activities surrounding return of results, a large majority of respondents (78%) said researchers conducting studies involving human genetics should routinely be required to provide detailed information to the IRB up front, in the protocol submitted for review, addressing disclosure of individual genetic results **to participants** (i.e., whether or not any results might be disclosed and, if so, what kinds and by what process). A smaller proportion, but still a majority (65%), said researchers should routinely address disclosure **to family members**; most others (31%) said this information should be required only if the prospect of offering results to family members is likely (e.g., based on the nature of the study).

Finally, we asked, "When researchers have generated genetic results that they believe should be offered to participants and/or family members, **should they be required to consult with the IRB prior to initiating contact**?" Only 14% of respondents said this should happen routinely; 75% said consultation is necessary only if such plans were *not* included in researchers' approved protocol, or if researchers wanted to modify their approved plan.

Discussion

Offering research results to participants continues to gain acceptance with the premise that participants deserve to know the outcome of research to which they contributed.[7] Although many issues remain unresolved — for example, the appropriateness of offering aggregate[8] versus individual results,[9] and how to handle logistics and cost[10] — this new landscape is further challenged by genetic research. Genetic research produces large numbers of results that are of potential interest not only to research participants, but in some cases may be informative for participants' family members.

The goals of this study were to assess IRB perspectives on 1) offering genetic research results to participants and family members, and 2) the role of the IRB in developing, implementing, and overseeing policies

Table 4b

If Not the IRB, Who Should Have Authority for Considering Disclosure of Specific Individual Genetic Research Results?

Consideration of Specific Results	The researcher		Existing institutional entity		Ad hoc institutional entity		National entity		Unsure	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Determining whether an actual genetic result **meets the criteria for disclosure** to participants and/or family members (n=31)	11	(35)	4	(13)	7	(23)	5	(16)	4	(13)
Determining the **specific process** by which participants and/or family members are contacted and offered an actual genetic result (n=26)	11	(42)	0	(0)	5	(19)	5	(19)	5	(19)

Percentages may not sum to 100% due to missing data

and procedures for offering results. With regard to the first, many of our survey questions focused on a scenario involving a disease-specific biobank, research results that were clinically valid and had potential but unproven utility, and a consent form that stated results might be offered if "useful for your health care or your family members' health care." Although it will be important for future research to explore perspectives on genetic results that have other combinations of validity and utility, we believe the lack of established utility for the *CDKN2A* variant in our scenario reflects what may be a very common challenge for IRBs — that is, the situation where there is potential actionability but no data yet available to support (or refute) the effectiveness of an intervention among those who have the variant.

In this context, a large majority of our respondents favored offering the result to research participants. They also favored offering participants one or more choices at the time of initial consent about receipt of their own results. In general, these findings are in keeping with consensus statements recommending that individual genetic research results should be offered when they are valid, medically important and actionable, and the participant has actively agreed to receive them.[11] To the extent our findings appear to depart somewhat from broad recommendations concerning the need for clinical utility, they may reflect an inclination to assign slightly more weight to the importance of clinical validity when considering the return of a specific result. This would be consistent with other empirical research on IRB perspectives,[12] which points to the centrality of clinical validity and participant consent, together with considerations of clinical utility, in the decision to offer results.

In contrast to offering results to research participants, most consensus statements have been silent on the topic of sharing results with participants' families. We made the presumption that when a research participant is alive, he or she would control disclosure of results to others; thus, our survey questions were based on the situation of a deceased participant. Given the same disease-specific scenario, most of our survey respondents did not endorse offering a deceased participant's results to family members. Alternative consent statements about the possibility of offering results to family members had some effect on respondents' opinions, but were not necessarily determinative. Notably, a substantial majority of our respondents indicated that a participant's choices about offering results to family members, once elicited, were determinative and should be honored even after death.

The second goal of our survey was to investigate IRB chairs' perspectives on the role of the IRB in offering research results. Consensus statements typically recommend a prominent role for IRBs, including the development of guidance on the characteristics of results that should be offered, decisions about over-riding participant choices about whether results should be offered, the advisability of disclosing specific results, processes for re-identifying and contacting participants, review and approval of researchers' plans regarding return of results, and ongoing oversight and consultation regarding implementation of the plan.[13]

Assigning the totality of these tasks to the IRB, however, may reflect the absence of a ready alternative. In fact, our survey responses suggest that many IRB chairs view their proper role as more limited. In general, respondents commonly indicated the IRB should have full authority with regard to approval of processes (e.g., by which participants and/or family members are contacted and offered results), but have more limited input on medical/scientific questions. For example, many respondents identified "the researcher" as the proper authority for determining whether an actual result meets the criteria for disclosure. This prominent role for researchers may reflect a perception that they likely have the best understanding of the scientific and medical importance of their particular finding — or that there is no other entity available to take on this role. Further research is needed to explore these issues in depth. In the meantime, our findings are consistent with a smaller qualitative study by Dressler et al.,[15] which suggested an oversight role whereby the IRB would not be involved in decision making about returning a particular result, but rather would ensure that an appropriate, ethical process is followed for making decisions and communicating with participants.

Thus, a fundamental challenge in addressing return of individual research results is whether or not this is within the scope of IRB authority/responsibility. IRBs are tasked with protecting the rights and welfare of human subjects in research, where the explicit goal is generalizable knowledge, not individual benefit.[15] Offering individual genetic results optimizes individual interests and values, and if those results inform medical decision-making, returning results may cross the boundary into clinical care. This puts the IRB in a curious position in terms of offering results to individual participants. Genetic results are only now being introduced into routine clinical care in a very institution-dependent (if not physician-dependent) way, and yet at least some portion of the public is actively seeking genetic information through direct-to-consumer genetic testing and possibly research participation. At what point is this clinical care? And the IRB's position

is even more curious when it comes to any responsibility regarding offering results to family members who are not research participants, particularly when the reason for offering results is to inform family members of a possible health consequence. Elsewhere in this special issue, Wolf, Burke, and Koenig discuss the blurring of boundaries between research and clinical care raised by the challenge of return of results.[16]

In our survey, IRB chairs often suggested that a national entity should provide guidance concerning which results merit return, and to whom. In the absence of such guidance, determination of what is "return-worthy" will be a local phenomenon and will differ between institutions. This is a particular concern in the face of increasing multi-site research and the use of national research resources. In addition to identifying what should be returned — with scientific and clinical confidence — a number of complementary local mechanisms are needed to support IRBs and researchers when implementing the return of genetic research results. These include the ability to confirm the result, if need be, in a CLIA-approved environment, and processes for providing education and referral as appropriate. In addition, although our respondents' self-reported involvement in dbGaP-related research requirements was not high, many endorsed the idea that promises made in consent forms about return of results should be "passed through" to users of dbGaP — a finding that, if borne out, would add yet another layer to an already complicated situation. It is not obvious that all of these tasks fall within the scope of IRB oversight and in-depth discussion of appropriate mechanisms is warranted.

To our knowledge, topics our survey addressed have not been previously studied among IRBs and they have important policy implications. Our survey of U.S. IRB chairs, complemented by findings found elsewhere in this special issue from their Canadian counterparts,[17] and from research participants,[18] provides initial data to inform future discussions and research. Further qualitative research and deliberation with IRB leaders, investigators, healthcare providers, research participants, and family members are needed to develop ethical policies, procedures, and oversight mechanisms — and to define the roles and responsibilities of each party — for when and how research results should be offered to participants and families. The Working Group report[19] in this issue of *JLME* is an example of constructive deliberation by key stakeholders.

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