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Returning Genetic Research Results: Considerations for Existing No-Return and Future Biobanks

Karen J. Maschke*

I. INTRODUCTION

A pressing issue for the genetic research enterprise—and an issue that has important implications for biobanks—is whether researchers should share, or “return,” the genetic research results with the individuals whose DNA they studied.1 With some exceptions, researchers typically have not returned genetic research results to the biospecimen donors.2 One reason for a no-return policy is that researchers typically study DNA samples that have been stripped of personal identifiers, making it difficult or impossible to link information about specific samples to their donors.3 Even if individuals can be re-identified, most genetic research results have uncertain clinical significance.4 Nonetheless, some commentators—including prospective

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2. See Christopher Heaney et al., Researcher Practices on Returning Genetic Research Results, 14 GENETIC TESTING AND MOLECULAR BIOMARKERS 821, 821 (2010) (reporting that twenty-four percent of surveyed authors of genetic or genomic studies returned results).

3. Wolf et al., supra note 1, at 369.

4. See id. at 368 (raising the concern that research participants might “mistake research for clinical care” and the process “may involve return of findings that are not adequately understood and validated”).
tive and actual biospecimen donors—contend that donors should have access to their own genetic information, even if its clinical significance is uncertain. As evidence emerges that some genetic information does have clinical significance, a consensus is emerging among a wide range of stakeholders for a conditional-return approach, which would entail returning some results to biospecimen donors.

A recent set of recommendations by Wolf et al., for a conditional-return approach is directed specifically to biobanks. Biobanks are resources for scientific research, containing human biospecimens such as blood, saliva, and tissue samples—healthy and diseased—from surgical and diagnostic procedures. Many biobanks also contain personal health information about the biospecimen donors and the data researchers derive from their studies. Although not new, "biobanks have become crucial to the conduct of genetic and genomic research, especially large-scale genomic research." Biobanks provide researchers with ready access to biospecimens and data, thus de-

5. Erin D. Harris et al., The Beliefs, Motivations, and Expectations of Parents Who Have Enrolled their Children in a Genetic Biorepository, 14 GENETICS IN MED. 330, passim (2012); Daniel MacArthur, When "Cautious" Means "Useless," WIRED SCI. BLOG (Feb. 18, 2011, 12:17 PM), http://www.wired.com/wiredscience/2011/02/when-cautious-means-useless/ (arguing that information should be returned to participants even if it is not "actionable").

6. See Ebony Bookman et al., Reporting Genetic Results in Research Studies: Summary and Recommendations of an NHLBI Working Group, 140A AM. J. MED. GENETICS 1033, 1033 (2006) (concluding that results should only be returned to participants if the "associated risk for disease is significant"); Richard R. Fabsitz et al., Ethical and Practical Guidelines for Reporting Genetic Research Results to Study Participants, 3 CIRCULATION: CARDIOVASCULAR GENETICS 574, 575 (2010) (offering a list of conditions that, if satisfied, would warrant the return of research results); Vardit Ravitsky & Benjamin S. Wilfond, Disclosing Individual Genetic Results to Research Participants, 6 AM. J. BIOETHICS 8, 8 (2006) ("The ethical principles of beneficence, respect, reciprocity, and justice provide justification for routinely offering certain results to research participants."); Wolf, supra note 1, at 378 (stating that some findings should be offered back to the contributor); Susan M. Wolf et al., Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations, 36 J. L. MED & ETHICS 219, 230 tbl.3 (2008) [hereinafter Wolf II] (comparing recommendations as to when individual research results should be returned to the participant).

7. See Wolf et al., supra note 1, at 361.

8. See id. at 363 ("A biobank is a structured resource that holds human biological samples and/or data to facilitate research over time.").

9. Id.
creasing the time and expense of collecting those materials on their own. Because biobanks are a central part of a “biobank research system,” Wolf et al. argue that they shoulder significant responsibilities for managing the return of genetic research results to biospecimen donors.

The ethical justifications for returning genetic research results and the criteria suggested for determining when results are returnable are beyond the scope of this paper. Rather, this paper will identify several ethical and practical issues that existing biobanks with a no-return policy, and future biobanks, will have to consider in determining whether and how to return genetic research results to biospecimen donors. These issues involve the consent status of biospecimens and data, the “identifiability” of those materials, the analytical validity of genetic research results, and the disclosure process. Finally, this paper suggests that at medical institutions with multiple conditional-return biobanks, decision-making regarding the criteria for what results are returnable should take place at the institutional level, rather than at the level of individual biobanks.

II. GENETIC RESEARCH RESULTS: EXISTING NO-RETURN AND FUTURE BIOBANKS

Biobanks have three options for managing genetic research results: 1) never share results with the individuals whose DNA was analyzed (no-return approach); 2) return some results to some individuals (conditional-return approach); or 3) return all of the genetic information generated by the DNA analysis to the individual donors (always-return approach). The limited empirical data regarding biobanks in the U.S. suggest that most biobanks use the no-return approach. The known exceptions are several new large-scale biobanks that use the conditional-return approach.

10. See Panel on Collecting, Storing, Accessing, and Prot. Biological Specimens and Biodata in Soc. Surveys et al., Conducting Biosocial Surveys 41 (2010) (“One of the advantages of collecting biological specimens as part of social surveys is that digital representations of the data derived from the specimens... can be appended to the survey data and shared with other researchers. Wide dissemination of data facilitates advances in research and public policy”).

11. Wolf et al., supra note 1, at 362.

tional-return approach. At least one biobank, the Personal Genome Project, comes closest to meeting the definition of an always-return approach where participants are given all genetic information derived from the research analysis of their biospecimen.

A. IDENTIFIABILITY AND CONSENT ISSUES

Given the compelling ethical justifications for returning genetic research results having clinical significance, a threshold question for future biobanks is whether they should be designed so that no results are ever returned to individual biospecimen donors. Some may suggest the answer is yes, even if there is a possibility that some research results will have clinical significance. At least one new biobank, Vanderbilt University’s BioVU, irreversibly de-identifies the DNA samples and data it collects, meaning that genetic research results can never be returned to the biospecimen donors.

For an existing no-return biobank, the identifiability issue raises at least two scenarios. If the biobank irreversibly de-identifies biospecimens and data, it can never return genetic research results to the biospecimen donors. However, if the biobank is still collecting biospecimens and data, it could apply the conditional- or always-return approach to the newly collected materials. This scenario raises the question of whether an

13. See, e.g., Leslie G. Biesecker et al., The ClinSeq Project: Piloting Large-Scale Genome Sequencing for Research in Genomic Medicine, 19 GENOME RES. 1665, 1667 (2009) (informing participants that they will be contacted “to determine if they are interested in learning about clinically relevant results”); Frequently Asked Questions, CORIELL, http://cpmc.coriell.org/Sections/About/FAQs.aspx?PId=13 (last visited Jan. 29, 2012) (stating that participants will not be informed of results for which there is not treatment or intervention available for treating the disease); Informed Cohort, The Gene Partnership, CHILD. HOSP. BOSTON, http://www.genepartnership.org/about-tgp/informed-cohort/ (last visited Jan. 29, 2012) (research subjects are part of an “informed cohort,” participating as “partners in their own research”).

14. See How it Works, PERS. GENOME PROJECT, http://www.personalgenomes.org/howitworks.html (last updated Apr. 1, 2011) (“Once the PGP has completed the analysis of your specimen(s), the PGP will make the data available to you”).

15. See Wolf et al., supra note 1, at 367–68 (discussing ethical concerns surrounding return of research findings).

existing no-return biobank that irreversibly de-identifies biospecimens and data should change this approach so that some, if not all, results can be returned to new biospecimen donors. Or like a new biobank that irreversibly de-identifies biospecimens and data so that genetic results can never be returned to biospecimen donors, is it ethically justifiable for an existing no-return biobank to continue that approach?

Even if an existing no-return biobank can link genetic results to a specific individual’s DNA sample, several consent-related issues must be addressed to move from a no-return to a conditional- or always-return approach. For example, were the biospecimens and data obtained with consent from individual donors for use in research, including genetic research? What if the no-return identifiable biobank holds residual biospecimens derived from surgical and diagnostic procedures that are linked to personal identifiers but that were obtained without consent for research? What if the biobank holds identifiable materials collected with consent for specific research, but the materials were not irreversibly de-identified and used for different research?

Anecdotal reports suggest that many medical research institutions control biobanks containing biospecimens that were obtained without consent for research or whose consent status is uncertain. Yet some individuals might be upset to learn that their DNA was used in research without their consent or may not welcome a biobank contacting them regarding the genetic information researchers discovered. Alternatively, what if genetic research results have clinical significance in the sense that preventive or treatment approaches are available? Does a biobank have a duty to offer clinically significant results to individuals if they did not know their biospecimens were kept

17. See generally Wolf II, supra note 6, at 227 (“[R]esearchers have an obligation to address the possibility of discovering IFs not only in their protocol and communications with the IRB, but also in their consent forms and communications with those being recruited to the study and research participants”).

18. See ROBERT F. WEIR & ROBERT S. OLICK, THE STORED TISSUE ISSUE: BIOMEDICAL RESEARCH, ETHICS, AND LAW IN THE ERA OF GENOMIC MEDICINE 26 (2004) (“Tissue has frequently been collected without appropriate disclosure to patients and research participants about why tissues are needed for research purposes and what investigators plan or hope to do with them”).

19. See, e.g., Ellen Wright Clayton, Incidental Findings in Genetics Research Using Archived DNA, 36 J.L. MED. & ETHICS 286, 290 (2008) (stating that research participants want to receive incidental findings, but the way that information is disclosed is important).
and used for research and if the consent form was silent or vague about returning results?²⁰

For existing no-return biobanks that collected biospecimens and data from individuals who gave consent for their use in research, the first step is to determine what, if anything, the consent form says about research results. Does the consent form explicitly state that no genetic results will be returned, is it silent on the issue of returning results, or does it mention results but contain vague language about the matter? A recent empirical study of publicly available documents from selected biobanks in the United States found that less than half addressed the issue of returning research results in some manner.²¹

Regardless of whether the consent form for an existing no-return biobank says anything about research results, does it explain whether the biobank will or may re-contact biospecimen contributors? If re-contact is mentioned, does the consent form give individuals the opportunity to decline to be re-contacted, or is being re-contacted a condition of enrolling in the biobank? One option is to maintain the no-return policy for the biospecimens and data already in the biobank, but use the conditional-return approach with future biospecimen donors who are informed about the new policy for returning genetic research results.

Another consent issue that has yet to be fully addressed in the return-of-results literature involves genetic research results generated after a biospecimen contributor has died. Should genetic information be shared with the decedent's relatives?²² No empirical data is available documenting how biobanks address this issue, although the publicly-available consent forms of two new large-scale conditional-return ap-

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²⁰. See Laura Beskow & Wylie Burke, Offering Individual Genetic Research Results: Context Matters, 2 SCI. TRANSLATIONAL MED. 1, 4 tbl.1 (2010) (comparing different obligations to share information based on the research context).

²¹. Johnson et al., supra note 12, at 4 (noting that seven (sixteen percent) of the forty-three biobanks surveyed returned information to participants while fourteen (thirty-three percent) did not).

²². See Anne Marie Tassé, Biobanking and Deceased Persons, 130 HUM. GENETICS 415, 419 (2011) (discussing the considerations that must be addressed when making the determination to return genetic results to the family members of deceased donors).
proach biobanks indicates that they do not do so.\textsuperscript{23}

Some commentators may argue that a consent form is not a contract in the sense that omissions in the document regarding matters such as re-contacting research participants or offering them research results from analyses of their DNA mean that such activities are prohibited. However, as noted above, others contend that contacting individuals who are unaware that their DNA was used in research raises several concerns.\textsuperscript{24} Little empirical data are available regarding IRB members’ perspectives about consent issues related to the return of genetic results. However, several studies indicate that with regard to other consent-related matters, IRB members have differing opinions about when reconsent is ethically necessary.\textsuperscript{25}

As to the issue of returning genetic research results to the relatives of decedents, state and federal privacy laws may prohibit the disclosure of genetic information without consent from the individual whose information is at issue.\textsuperscript{26} Future biobanks using a conditional-return approach may consider asking biospecimen donors whether they want the biobank to share genetic research results with their relatives if the results are obtained post-mortem. Existing no-return biobanks still collecting biospecimens that ultimately adopt the conditional-return approach could do the same. For an existing conditional-return

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24. See generally Clayton, supra note 19, at 287 (stating that some patients, like those at research hospitals, have no idea that their samples might be used for current or future research and even those who know that their samples will be used don’t know to what extent).


26. \textsc{Weir & Olick}, supra note 18, at 139 (“The federal policy makes duties of confidentiality clear, but is largely deferential to state law and local practice regarding the rules and methods for meeting this obligation.”).
\end{flushleft}
biobank whose consent form is silent on the issue, it is unclear whether the biobank has an ethical “duty to warn” relatives about genetic information that might have clinical significance for them.27 How IRBs will respond if a biobank wants to offer genetic results to a deceased donor’s relatives remains to be seen.

B. THE CLIA ISSUE

If existing no-return and future biobanks decide to return some genetic research results to study participants, they must also decide whether to return only results that were generated in a laboratory complying with the certification requirements of the Clinical Laboratory Amendments of 1988 (CLIA).28 CLIA and accompanying regulations require laboratories that report “patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients” to be CLIA certified.29 Since research laboratories do not report results to clinicians, most are not CLIA certified. Nonetheless, several conditional-return biobanks offer only CLIA-validated results to participants.30 Commentators disagree about how to interpret CLIA requirements in the research context. According to Roberts et al., if the original genetic testing was not conducted in a CLIA-certified laboratory and “the decision to communicate research results is because of their potential clinical significance, retesting should occur in a CLIA-certified laboratory.”31 But they

27. See Beskow & Burke, supra note 20, at 1–2 (suggesting that researchers may have an ethical “duty to rescue” when “an investigator discovers genetic information that clearly indicates a high probability of a serious condition for which an effective intervention is readily available”); Marni J. Falk et al., Medical Geneticists’ Duty to Warn At-Risk Relatives for Genetic Disease, 120A AM. J. MED. GENETICS 374, 375 (2003) (stating the alternative positions of putting the responsibility on the researcher to disclose versus leaving that responsibility to the individual having the testing).


contend that if the genetic results “are communicated because of non-clinical value, such as personal meaning (or because response to research results was what was being assessed in the study), CLIA certification is not necessarily required.” The consent form for the Roberts study explained that the tests would not be conducted in a CLIA-certified laboratory and that participants could have their results CLIA validated at their own expense. Some institutions may require genetic research results to be CLIA-validated before they are offered to biospecimen donors. Yet in a study of IRB chairs’ perspectives about returning genetic research results, two examples were described in which an IRB overruled its own guidance that only results obtained in a CLIA-certified laboratory could be returned to research participants. Although some representatives from the Centers for Medicare & Medicaid Services (“CMS”)—the federal agency that enforces CLIA—have stated that “test results returned to individuals are always considered subject to CLIA,” it remains unclear how CMS will respond if biobanks (or individual researchers) return genetic research results to biospecimen contributors that were not obtained in a CLIA-certified laboratory.

C. DISCLOSURE CONSIDERATIONS

Another important consideration for existing no-return and future biobanks that decide to adopt the conditional- or always-return approach is how to manage the disclosure process. Despite claims that genetic information is not exceptional vis-a-vis other medical information—such as results from blood tests or x-rays—genetic information is often treated exceptionally.

Indeed, specialized genetic counselors often help individu-

32. Id.
33. Id. at 20–21.
34. Lynn G. Dressler et al., IRB Perspectives on the Return of Individual Results from Genomic Research, 14 GENETICS MED. 215, 217 (2012).
36. Thomas H. Murray, Genetic Exceptionalism and “Future Diaries”: Is Genetic Information Different from Other Medical Information?, in GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA 60, 61 (Mark A. Rothstein ed.,1977) (defining genetic exceptionalism “to mean roughly the claim that genetic information is sufficiently different from other kinds of health-related information that deserves special protection” and stating that genes are “uniquely personal” and thus require that protection).
als interpret and understand their genetic test information, a practice unique to genetic research.\textsuperscript{37} If biobanks adopt the conditional- or always-return approach, should they require individuals to obtain the results from a genetic counselor and undergo formal genetic counseling? If a biobank requires genetic counseling as a condition of receiving genetic research results, who pays for the counseling? Even if genetic counseling is not required, should results be disclosed by a genetic counselor or by the donors’ physician? Does disclosure of results have to involve personal interaction or may results be disclosed by mail, telephone, or through electronic forms of communication? Some parents whose children are participating in biobank research say they prefer to receive their child’s results electronically,\textsuperscript{38} and adult biobank participants may be open to receiving their results by telephone, regular mail, or e-mail.\textsuperscript{39} The Coriell Personalized Medicine Collaborative and the Gene Partnership are integrating innovative web-based portals and personal health records platforms into their disclosure process.\textsuperscript{40} These disclosure approaches diverge from standard approaches involving one or more face-to-face meetings with a genetic counselor to receive genetic test information, and raise issues about a biobank’s capacity to develop and implement innovative disclosure strategies.

D. INFRASTRUCTURE AND CAPACITY

Shifting the focus from the individuals whose DNA researchers analyze to the researchers themselves implicates another set of considerations. For instance, an existing no-return biobank that changes to a conditional- or always-return approach will need to consider whether the new policy will affect researchers who have already received biospecimens and data from the biobank, or only researchers who receive materials after a certain date. Biobanks will also need to inform research-


\textsuperscript{38} Harris et al., supra note 5.

\textsuperscript{39} See, e.g., David I. Shalowitz & Frank G. Miller, Communicating the Results of Clinical Research to Participants: Attitudes, Practices and Future Directions, 5 PLoS MED. 714, 718–19 (2008) (“[P]articipants often prefer to receive results in writing with contact information.”)

\textsuperscript{40} See Frequently Asked Questions, supra note 13.
ers about what results will or may be offered to individuals, what they are to do with such results, and how the disclosure process works. Biobanks could consider using material transfer and data access agreements to stipulate the conditions under which researchers should report results to the biobank that will or may be returned to individuals. However, researchers typically are prohibited by material transfer and data use agreements from re-identifying or contacting the individuals whose materials they received and used in their studies.

All of the considerations discussed above raise an issue about the capacity—defined broadly—of an existing no-return biobank or future biobank to adopt a conditional- or always-return approach. A broad definition of capacity includes a range of considerations about personnel, biospecimen and data tracking, information technology (IT), requirements for review and approval of a return approach by the IRB and/or other oversight committees, CLIA testing, and the specifics of the disclosure process. All of these considerations translate into additional costs for an existing no-return biobank, as well as for future biobanks. From a normative perspective, should cost issues regarding capacity be determinative for existing no-return biobanks and for future biobanks?

III. RETURNABLE RESULTS: WHO DECIDES?

A key question that arises when adopting the conditional-return approach is who should decide what results are returnable? Some commentators have suggested that biobanks could establish a specialized committee separate from the IRB to be the decision-maker, and several new biobanks—the Coriell Personalized Medicine Collaborative, the Gene Partnership at Boston Children’s Hospital, and the Mayo Clinic Biobank—have adopted this approach. The committee at the Coriell Personalized Medicine Collaborative is the Informed Consent

41. Marianna J. Bledsoe et al., Practical Implementation of Issues and Challenges for Biobanks in the Return of Individual Research Results, GENETICS MED. 1, 2–3 (2012), http://www.nature.com/gim/journal/vaop/ncurrent/pdf/gim201167a.pdf (noting that biobanks will have to consider a host of practical issues if they decide to return results to individual donors) (advance online publication); Michael Ferriere & Brian Van Ness, Return of Individual Research Results and Incidental Findings in the Clinical Trials Cooperative Group Setting, GENETICS MED. 1, 6 (2012), http://www.nature.com/gim/journal/vaop/ncurrent/pdf/gim201214a.pdf (advance online publication); Wolf et al., supra note 1.
The Gene Partnership created the Informed Cohort Oversight Board (ICOB) and the Mayo Clinic Biobank created the Biospecimen Trust Oversight Group (BTOG). The IRBs that approved the protocols for these biobanks did so with the understanding that the biobanks would create a specialized committee to determine what results to return to biospecimen donors.

Yet left unaddressed in the literature on the return of results is who the decision-maker should be at medical institutions that have multiple conditional-return biobanks. Anecdotal evidence suggests that many medical institutions have multiple biobanks—ranging from small collections of healthy and diseased tissue to collections like the Mayo Clinic Biobank that hold thousands of specimens. Medical institutions with multiple conditional-return biobanks should consider developing an institutional return of results committee separate from the IRB to establish criteria for returnable results and to assist biobanks in determining when research findings meet those criteria.

One reason for an institutional return of results committee is to promote fair access to genetic research results. For instance, what if one biobank at an institution decides it will inform donors if they have the ApoE genotype, but another biobank at the same institution will not? Why should some biospecimen donors have access to that information, but not others? A further reason for an institutional return of results committee is that some results, like those that reveal gene variants related to drug metabolism, may be clinically actionable. It seems reasonable to suggest that institutions with multiple conditional-return biobanks should have a uniform approach to

42. See Frequently Asked Questions, supra note 13.
establishing the criteria for results that are clinically actionable so that all biospecimen donors will have access to results that have implications for their clinical care.

Some will object to creating yet another institutional committee and placing decision-making in such a committee rather with the IRB. Yet it is not self-evident that the IRB is the appropriate committee to establish the criteria for returnable results and to assist biobanks in determining when those criteria are met with regard to specific genetic findings. Many commentators claim that IRBs are unnecessarily overburdened with regulatory responsibilities regarding the protection of research participants. Moreover, some commentators complain about IRB “mission creep,” that is, assuming responsibility for matters beyond specific regulatory domains.

The Coriell Personalized Medicine Collaborative, the Gene Partnership and the Mayo Clinic Biobank have established a precedent for a return of results committee at the biobank level, and there is evidence that some commentators and IRB members are attracted to such a decision-making body separate from the IRB. For instance, at a workshop the National Cancer Institute convened in 2010 to address the issue of biospecimen donors’ research results, participants expressed varying opinions about whether the IRB should assume the role of institutional decision-maker about what results are returnable. One of the breakout groups “agreed that the IRB should review and approve proposed mechanisms for the return of research results” and that “when a potentially returnable research result arises, the investigator should notify the IRB and seek guidance on whether the result should be returned.” This breakout group also recommended that a “smart filter” be cre-

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ated, i.e., a list of criteria regarding what results are returnable, and that the IRB should use the filter “to evaluate the validity of the results and determine whether the results should be returned.” 48 Although this breakout group also said the “IRB may seek guidance from an advisory committee that includes members with expertise in the techniques used by the research,” it is unclear whether the group meant that the advisory committee, and not the IRB, should make the final determination about what results are returnable. 49

Yet, as previously noted, missing from the commentary about biobanks establishing criteria for returnable results is the recognition that many medical institutions likely have multiple biobanks that already return some results to donors or that may shift from a no-return to a conditional-return approach. The Coriell, Gene Partnership, and Mayo models include members with expertise in genetics, medicine, and bioethics. The committees for those biobanks also include community members from the general public.

In addition to the precedent established by the Coriell Personalized Medicine Collaborative, the Gene Partnership, and the Mayo Clinic Biobank, there is additional precedent for institutional-level committees that are parallel to and work in tandem with the IRB. For instance, some institutions have an institutional conflict of interest committee that establishes financial and other disclosure requirements for researchers, including what information to disclose to the IRB at the protocol review stage. 50 And many institutions have separate oversight committees that review protocols for embryonic stem cell research. 51 Finally, several institutional members of the NIH’s Clinical and Translational Science Awards program have developed a research ethics consultation service that complements, but is separate from, the IRB. 52

48. Id. at 35.
49. Id. at 36.
IV. CONCLUSION

In recent years, several groups and individual commentators have made a compelling case that researchers and biobanks have an ethical obligation to return some, if not all, genetic research results to the individuals whose DNA researchers studied.53 These calls for a conditional-return approach raise a host of ethical and practical considerations for existing no-return biobanks, as well as for future biobanks. No-return biobanks that can link genetic results to a specific donor’s DNA sample will need to consider whether the ethical arguments in favor of the conditional-return approach compel them to change their policy. Future biobanks will have to decide whether it is ethically justifiable to irreversibly de-identify biospecimens, since doing so means that genetic results can never be returned to donors.

Shifting from a no-return to a conditional-return approach implicates issues that IRBs will have to address regarding the original consent of biospecimen donors and the disclosure process. Adding to the complexity of the issue regarding the conditional-return approach is that many biobanks in the U.S. are located in medical institutions that have multiple biobanks.54 The proposal here is for an institutional return of results committee to establish the criteria for returnable results shifts decision-making away from individual biobanks and the IRB, and creates the opportunity for consistent and fair policies across all of an institution’s conditional-return biobanks.

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53. See e.g., Bookman et al., supra note 6; Fabsitz et al., supra note; Wolf et al., supra note 1; Wolf II, supra note 6.