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INTRODUCTION

While attention to the issue of incidental findings (IFs) arising specifically in the context of biobanks and secondary research is relatively new, it marks the convergence of two more developed areas of inquiry—what to do with IFs arising from biomedical research generally and what to do with biological specimens and data containing DNA information once they have been extracted from their human sources.[1] When they first garnered attention, these two areas of inquiry were largely the focus of bioethical questions:

- What benefits and harms, if any, do IFs pose for human subjects?[2]

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1. The term by which we should refer to the individuals from whom specimens or DNA data are extracted and used for research has been debated in the literature, including in the consensus report that serves as the center for this Symposium. *See* Susan M. Wolf et al., Special Article, *Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets*, 14 GENETICS MED. 361, 364 (2012). As explained by Wolf et al. and in Part I of this paper, these individuals do not fall within the federal regulatory definition of "human subjects" if they cannot be readily identified by the researchers using their specimens or data and if their specimens or data were collected either for purposes other than the research in question or by another institution that has stripped and retained individually identifying information from the specimens or data. The issues addressed in this paper and in the consensus report, however, involve both individuals who meet this regulatory definition of "human subject" and those who do not. The consensus report adopts the term "contributors" to refer to individuals whose specimens or data are extracted and used for research regardless of whether they also qualify as "human subjects" under federal regulations. *Id*. We, however, choose here to use the term "human sources" as we find that "contributors" implies a decision by these individuals to contribute to research, whereas many of the issues for concern posed in this paper pertain to situations in which the individual was given no opportunity to make such a decision to contribute. Thus, the reader should bear in mind that, for the purposes of this paper, "human subjects" are all "human sources" but not all "human sources" are human subjects."

2. In this paper, we use "human research subjects" to refer broadly to individuals whose specimens and data are used in the course of research, including human sources agreeing to participate in research and human sources whose specimens and data are used in research without their knowledge or consent. However, as explained in Part I, current guidance from the Office for Human Research Protections (OHRP) advises that human sources are human subjects but that researchers are not engaged in human subjects research when the specimens and data used in research were not collected for the purposes of that research and are not readily identifiable by

- What rights, if any, should human subjects have to be informed of IFs?[3]
- What duties, if any, do researchers bear to inform human subjects about IFs?
- To whom do specimens and data containing DNA information belong once they have been extracted from their human sources?
- What rights, if any, do human sources of such specimens and data have to decide when, by whom, and for what purpose their DNA information can be used in research?

Indeed, earlier ethical and legal analysis of the issues surrounding IFs put forth conclusions such as:

> We argue that researchers owe research participants duties that are both ethical and legal obligations: to disclose in the informed consent process the possibility of discovering IFs and the plan for management; to recognize an IF that arises during the course of research; to verify the presence of the IF and evaluate its probable importance, obtaining expert consultation if necessary; and to offer to disclose an IF of likely clinical or reproductive importance to the research participant.[4]

> To treat someone as a mere means to gathering proteins or genes or to observing the interaction between T-cells and virus is to treat them as a mere means, period. What it takes, in this context, to treat them also "as an end" thus becomes the question. If research participants had full information about their condition and have attained a full understanding of the nature and the risks of the procedures involved in the research, securing their informed consent to participation would probably suffice . . . . Research participants generally lack this full understanding. Further, as the case of incidental findings again shows, they enter studies lacking full knowledge about their own medical conditions . . . . Given the lack of

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the researchers. *See* OFFICE FOR HUMAN RESEARCH PROTS., U.S. DEP'T OF HEALTH AND HUMAN SERVS., GUIDANCE ON ENGAGEMENT OF INSTITUTIONS IN HUMAN SUBJECTS RESEARCH (2008) [hereinafter GUIDANCE], *available at* http://www.hhs.gov/ohrp/policy/engage08.html. Similarly, OHRP provides that human sources are not human subjects at all for the purposes of research using biospecimens and data obtained from another institution and coded to prevent researchers from accessing any individually identifiable information. OFFICE FOR HUMAN RESEARCH PROTS., U.S. DEP'T OF HEALTH AND HUMAN SERVS., GUIDANCE ON RESEARCH INVOLVING CODED PRIVATE INFORMATION OR BIOLOGICAL SPECIMENS (2008); 45 C.F.R. § 46 (2011).

3. For our purposes, informing a human subject's physician or health care provider of the IF and allowing that health care provider with the professional relationship with the human source to decide whether and how to communicate the IF to the human source is the same as informing the human source of the IF.

4. Susan M. Wolf, Jordan Paradise & Charlisse Caga-anan, *The Law of Incidental Findings in Human Subjects Research: Establishing Researchers' Duties*, 36 J.L. MED. & ETHICS 361, 362 (2008).

> full information and given the huge average asymmetry in knowledge and understanding between the researchers on the one side and research participants on the other, we should conclude that the procedural safeguard of informed consent does not ensure that research participants are treated "also as ends."[5]
>
> We reject this position [that investigators have no obligations] in favor of the view that investigators do have limited obligations to inform subjects of incidental health-related findings. There are at least three potential sources for such obligations . . . . First, if the investigator (or another on her research team) is a physician, these obligations might derive from the nature of a physician's professional duties. Second, they might derive from duties rooted in general beneficence, independent of any professional or other relationship between the parties. Finally, and most persuasively, they might derive from the nature of professional responsibility generally or professional responsibility in the investigator-subject relationship. Considering these possibilities, it turns out, sheds light not only on investigators' duties regarding incidental findings, but more fundamentally on the nature of the investigator-subject relationship itself.[6]

An interest in controlling the use of one's DNA that is grounded on human dignity need not adopt reductionist views about personhood or the relationship between DNA and identity. Particular uses of one's DNA, in research or otherwise, may be viewed as thwarting the will of moral agents where such uses impede or undermine specific goals held by those agents. For instance, individuals may oppose research on the genetics of certain behavioral or other traits, like intelligence or sexual orientation. Individuals might additionally believe that DNA, including or especially human DNA, should not be patented. In the absence of control over one's genetic material, however, researchers might well use an individual's DNA to conduct such experiments, or to isolate, copy, and patent an interesting gene.[7]

Similar examples abound. Against this backdrop of ethical and legal inquiry, genetic and genomic research has continued to rapidly evolve from individual single-site studies

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5. Henry S. Richardson, *Incidental Findings and Ancillary-Care Obligations*, 36 J.L. MED. & ETHICS 256, 263 (2008).

6. Franklin G. Miller, Michelle M. Mello, & Steven Joffe, *Incidental Findings in Human Subjects Research: What Do Investigators Owe Research Participants?*, 36 J.L. MED. & ETHICS 271, 272 (2008).

7. Natalie Ram, *Assigning Rights and Protecting Interests: Constructing Ethical and Efficient Legal Rights in Human Tissue Research*, 23 HARV. J.L. & TECH. 119, 125–26 (2009) (footnotes omitted).

into large-scale, high-yield, and, in a number of cases, high-profit enterprises.[8] These enterprises are supported increasingly by the rise of the so-called "biobank research system" in which human specimens and data containing DNA information are amassed from multiple primary collection sites, including clinical (i.e., hospitals) and primary research sources, and archived by large-scale biobanks for downstream use by secondary researchers. In 1999, the National Bioethics Advisory Commission (NBAC) reported that almost 300 million human biological specimens were being stored in the United States with over 20 million new specimens added annually.[9] Research conducted on these stored specimens and on DNA information derived from these specimens is often subject to federal oversight regulations, including most prominently the Department of Health and Human Services' (DHHS) Common Rule[10] and similar Food and Drug Administration (FDA) regulations[11] governing conduct in human subjects research and the Health Insurance Portability and Accountability Act (HIPAA)[12] imposing data security standards and limiting the research use and disclosure of certain types of health information.[13]

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8. *See, e.g.*, Steve Silberman, *The Flesh Files*, WIRED, June 2010, at 159, *available at* http://www.wired.com/magazine/2010/05/ff_biobanks/all/1 ("From drug development to assisted reproduction, progress in dozens of fields would be impossible without biobanks. They are the biological back end of data-driven medicine."). We also recognize that a number of academic or clinical researchers are increasingly dependent on biobank research systems for research grants, publications, tenure, and professional standing. *See, e.g.*, Greg Blackman, *Biobanking: Saving for the Future*, SCI. COMPUTING WORLD, Apr./May 2009, *available at* http://www.scientific-computing.com/features/feature.php?feature_id=232 ("[I]n a pharmaceutical or biotechnology environment, biobanks are used to store specimen data in support of clinical trials. . . . In a medical research institute, while the clinical trial context may also apply, the primary focus of a biobank is to serve Principle Investigators (PIs), which could be clinicians or PhD researchers.").

9. 1 NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 13 (1999).

10. 45 C.F.R. pt. 46 (2011).

11. 21 C.F.R. pts. 50, 56 (2011).

12. Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in 42 U.S.C. §§ 5, 18, 28, 29, 42, 44, 45).

13. Other regulatory requirements may also be pertinent to biobank research activities, including the Privacy Act. Regulatory requirements under these regimes are, for the purposes of this paper, largely similar to those raised under HIPAA and, thus, are not discussed in detail. *See, e.g.*, 5 U.S.C.A § 552(a) (West, 2012).

Under the Common Rule, researchers must typically obtain approval from a local Institutional Review Board (IRB) prior to commencing human subjects research.[14] The IRB approval must be based on a demonstration that the risks to human subjects associated with the research are minimized and are reasonable in relation to any anticipated benefits.[15] The Common Rule also requires that researchers obtain informed consent from human subjects for specific research activities based on explicit disclosures of research risks and benefits.[16] HIPAA similarly requires authorization from individuals before researchers can use or disclosure certain health information in the course of research.[17]

However, existing federal provisions and exclusions to these regulatory schemes allow researchers to avoid these requirements for IRB approval and informed consent/authorization by using existing specimen and data and recording information in a manner that prevents their human sources from being identified[18] or by using existing specimen and data that have already been deidentified or stripped of their individual identifiers.[19] The primary basis for these provisions and exclusions is that the only harms human sources face as a result of research using their specimens and data are those associated with privacy and the risk of identification,[20] and that deidentification effectively

14. 45 C.F.R. § 46.109 (2011).

15. 45 C.F.R. § 46.111(a)(1)–(2) (2011).

16. 45 C.F.R. § 46.116 (2011).

17. 45 C.F.R. § 164.508(a)(1).

18. *See* 45 C.F.R. § 46.101(b)(4) (2012); GUIDANCE, *supra* note 2.

19. *See* GUIDANCE, *supra* note 2. One can debate whether it is possible to ever actually de-identify biospecimens as it is possible to match DNA information extracted from a specimen to other available individually identifying information. DNA matching is essentially 100% accurate and much less likely to lead to errors as can happen with similar names or dates of birth. The rise of biobanks storing DNA information makes it increasingly easy to link that DNA information with DNA information extracted from biospecimens for identification purposes. For purposes of this article, we do not address whether DNA information can ever be truly de-identified.

20. *See* Greg Helgesson et al., *Ethical Framework for Previously Collected Biobank Samples*, 25 NATURE BIOTECHNOLOGY 973, 973 (2007) ("Having a biological sample stored in a biobank involves no direct physical risk to the donor once the sample has been obtained."); *see also* Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,513–14 (July 26, 2011) [hereinafter *ANPRM*] (to be codified at 45 C.F.R. pts. 46, 160, 164

"minimize[s] the risk of harm to individuals while maximizing benefit [from research] to the broader society."[21] Thus, according to this view, deidentification avails the human source of the same rights protected by the Common Rule and the IRB process.[22] Alternatively, these provisions and exclusions can be viewed as allowing deidentification to eliminate the regulatory obligations of researchers to individuals who would otherwise be regarded as human subjects and afforded rights under the regime of human subjects research protection.[23] Asaconsequence, some biobanks deliberately and permanently de-identify specimens and data prior to sharing them with downstream secondary researchers so that no obligations to human sources may exist.[24] The result is that secondary researchers may not have any contact with the human sources and may not know or be able to determine the sources' identities. Furthermore, human sources may be completely unaware that their specimens and data have been archived and are being used for secondary research or any research at all. Adding to this already complex picture is the potential for secondary research to turn up IFs of potential clinical significance to human sources. Questions loom as to what duties biobanks and secondary researchers have to disclose such IFs to human sources, and how such disclosures can even

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and 21 C.F.R. pts. 50, 56) ("[I]ncreasing use of genetic information, existing (i.e., stored) biospecimens, medical records, and administrative claims data in research has changed the nature of the risks and benefits of research participation. Risks related to these types of research are not physical but informational (e.g., resulting from the unauthorized release of information about subjects").

21. Jill Pulley et al., *Principles of Human Subjects Protections Applied in an Opt-Out, De-identified Biobank*, 3 CLINICAL & TRANSLATIONAL SCI. 42, 45 (2010).

22. *Id.*

23. *See, e.g.*, Katherine Drabiak-Syed, *State Codification of Federal Regulatory Ambiguities in Biobanking and Genetic Research*, 30 J. LEGAL MED. 299, 304 (2009) ("Currently, institutions may broadly collect specimens that have no accompanying identifying information to use for anonymized research without notification or obtaining a patient's consent. Ambiguity in federal law allows the possibility for institutions to build a biobank, by collecting leftover specimens and coded annotated information outside the scope of the Privacy Rule, to conduct genetic research without regulation or oversight.").

24. One such biobank is Vanderbilt University's BioVU. *See* Pulley et al., *supra* note 21, at 45; *BioVU: Vanderbilt's DNA Databank*, VANDERBILT UNIV., http://dbmi.mc.vanderbilt.edu/research/dnadatabank.html (last visited Apr. 20, 2012).

take place when it may be difficult or impossible to reidentify sources and when sources never consented to and are unaware of their involvement in research in the first place.

If at this point the reader is thinking that this multiplex of issues necessitates additional ethical and legal deliberation about the rights of human sources and the duties of biobanks and researchers, we have news for you—the issues are on the table but may be in the throes of what we see as a type of broad regulatory failure. We define this failure much like other forms of non-market failure where government policies produce ineffective results or distortions that undermine their very purpose.[25] We choose the term broad regulatory failure rather than government failure because the problem we describe involves not only formal oversight agencies such as DHHS and FDA, but also institutional oversight bodies like IRBs as well as complementary sources of oversight like standards of practice adopted by biobank research entities including primary collection sites (i.e., hospitals and primary researchers), biobanks, and secondary researchers.[26] As explained by Natalie Ram:

> For both researchers and society at large, simple and inexpensive access to the raw materials of research is critical to promoting investment in science and medicine. Researchers and those who fund research have a strong interest in minimizing roadblocks to research. Where there are fewer permissions to obtain, research can proceed more quickly and with less cost . . . . The addition and protection of more rigorous consent or other requirements designed to facilitate provider control over the use, disclosure, and commercialization of tissue may exacerbate these problems.[27]

Given the administrative burdens and delays to research that can result from requirements for informed consent and IRB review, biobank research entities have considerable incentive to take advantage of favorable interpretations of existing regulatory exclusions and exemptions provided under the Common Rule and HIPAA by deidentifying specimens and data and, thus, making reidentification of sources for the

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25. *See generally* Joseph E. Stiglitz, *Regulation and Failure*, *in* NEW PERSPECTIVES ON REGULATION 11–23 (David Moss and John Cisternino eds., 2009); Stephen Breyer, *Analyzing Regulatory Failure: Mismatches, Less Restrictive Alternatives, and Reform*, 92 HARVARD L. REV. 547 (1979).

26. As discussed in more detail below, state law requirements have not been addressed in prior analysis.

27. Ram, *supra* note 7, at 137–38.

purposes of disclosing IFs a moot point. IRBs, which are frequently cited as being chronically overextended,[28] have similar incentives to avoid advocating for disclosure of IFs from secondary research as this would add considerably to the number of protocols they would have to review and approve, increase the complexity of questions they would have to address in rendering such approvals, and place them in a position where they would retain complex oversight responsibilities for future secondary research.

In the summer of 2011, DHHS published an Advanced Notice of Proposed Rulemaking (ANPRM) to amend the Common Rule in light of recent advances that have changed the nature of biomedical research.[29] As justification for these proposed changes, DHHS cites the increasingly immense volume of and expenditures for biomedical research[30] and argues that risks to human participants in research using stored specimens and data are exclusively limited to informational risks associated with unauthorized disclosure of private information and do not include any physical, psychological, or other types of risks.[31] Thus, the ANPRM is not only silent on the issue of IFs arising from biobank research, but proposes amendments to the Common Rule that would encourage broader and more irreversible deidentification practices that, in essence, substantially reduce or eliminate (1) any rights of human sources to receive IFs; (2) any researcher obligations regarding return of IFs; (3) any researcher obligations to obtain specific informed consent for research using genetic information; and (4) any meaningful regulatory oversight of secondary research using biospecimens and DNA information obtained from biobanks.[32]

The good news for those concerned by this potential regulatory failure—and, perhaps, the bad news for those favoring status quo outcomes—is that federal law is not the

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28. *See, e.g.*, Lura Abbott and Christine Grady, *A Systematic Review of the Empirical Literature Evaluating IRBs: What We Know and What We Still Need to Learn*, 6 J. EMPIRICAL RESEARCH & HUMAN RESEARCH ETHICS 3, 3 (2011); C. K. Gunsalus et al., *Mission Creep in the IRB World*, 321 SCIENCE 1441, 1441 (2006).

29. *ANPRM*, *supra* note 20, at 44,51a2.

30. *Id.* at 44,513

31. *Id.* at 44,513–14.

32. At the time of this paper, the final rule amending the Common Rule has not been adopted. As such, we analyze the draft rule while recognizing that there may be changes.

supreme word dictating the outcome of complex biobank research issues. Indeed, many complex legal and ethical issues posed by biobank research, including issues of ownership of specimens and data, retention and use of archived specimens and data, genetic privacy, and informed consent, are already being and will likely continue to be decided not by federal and institutional authorities, but by state laws which to-date have not been federally preempted.

This is not some idle possibility. A number of recent judicial decisions reveal that researchers in full compliance with federal regulations may be subject to liability under state laws imposing higher informed consent and disclosure requirements.[33] Furthermore, because of the great variability of requirements across different states, biobank research activities that involve primary collection sites, secondary researchers, and human sources from different states likely face a formidable patchwork of laws under which they may face liability, as well as jurisdictions in which they can be sued.

In this paper, we explore what we think is the likely outcome for biobank research entities that choose to avoid disclosures of IFs but which are in full compliance with federal regulations. While disclosures of IFs are our central focus, we direct significant attention to the issue of informed consent as an unsettled and central element underpinning concerns with all rights and responsibilities arising under the biobank research system. In part I, we describe the enforcement and limits of IF disclosures from biobanks and secondary research under current and proposed federal regulatory requirements. In part II, we further describe the broad regulatory failure which may be taking place at the federal and institutional levels. In part III, we describe how the enforcement and limitations IF disclosures from biobanks and secondary research might play out in state courts. Finally, in part IV, we offer our points of consideration to biobanks, researchers, and state, federal, and institutional oversight authorities concerned with the eventual outcome of how rights and limits to IF disclosures will be enforced.

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33. *See, e.g.*, Bearder v. State of Minnesota, 806 N.W.2d 766 (Minn. 2011) (holding that the Minnesota Department of Health violated Minnesota's Genetic Privacy Act).

I. ENFORCEMENT OF RIGHTS AND LIMITS OF IF DISCLOSURES UNDER CURRENT AND PROPOSED FEDERAL REGULATIONS

The biobank research system is subject to federal human subjects research regulations most prominently codified under the DHHS Common Rule[34] and similar FDA regulations for human subjects protection,[35] as well as to federal privacy regulations under HIPAA.[36] These regulations attach to specific entities within the biobank research system, including collection sites, biobanks themselves, and secondary researchers, depending on the nature of the entities and the activities they undertake. While these federal regulations, both as they currently exist and under proposed changes put forth by the ANPRM, are silent on the issue of IFs, they do provide the framework by which we can assess when and how IF disclosures could take place.

The Common Rule "applies to all research involving human subjects conducted, supported or otherwise subject to regulation" by fifteen federal departments and agencies,[37] as well as to research by any institution claiming Federalwide Assurance (FWA) for the protection of human subjects by adopting the standards and rules articulated in the Common Rule.[38] FDA regulations for human subjects protection apply to all clinical investigations regulated by or in support of applications for research and approvals for products regulated by the FDA.[39] Both the Common Rule and FDA rules for human subjects protection typically require researchers to obtain informed consent from human subjects and approval from an IRB prior to commencing human subjects research.[40]

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34. 45 C.F.R. § 46 (2011).

35. 21 C.F.R. pts. 50, 56 (2011).

36. Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat, 1936 (1996) (codified as amended in scattered sections of 42 U.S.C.).

37. 45 C.F.R. § 46.101 (2011); *see also Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T HEALTH & HUMAN SERV., http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html (last visited Apr. 26, 2012).

38. *Federalwide Assurance (FWA) for the Protection of Human Subjects*, DEP'T OF HEALTH AND HUMAN SERVICES, http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html (last updated June 17, 2011).

39. 21 C.F.R. § 50.1 (2011).

40. 45 C.F.R. § 46.109, 46.116 (2011); 21 C.F.R. pt. 50, (a)–(B) (2011).

Requirements for IRB review and approval under both the Common Rule and FDA rules direct IRBs to evaluate ethical concerns posed based on assessments of several key factors including: minimization of risks to human subjects; reasonability of risks in relation to anticipated benefits, if any; adequacy of informed consent; sufficiency of data monitoring; and protection of human subjects' privacy and the confidentiality of data.[41] Informed consent is generally required for the specific research being conducted and, absent unusual situations, research participants can withdraw from the research at any time, for any reason, and without penalty.[42]

While these regulations do not provide a concrete definition of "risk," guidance for IRBs has identified risks to subjects as including physical, psychological, economic, and social risks.[43] Concerns associated with subjects' privacy and confidentiality of data have been framed as a set of issues separate from these other risks. These concerns pertain to subjects' informed consent to entrust investigators with access to their private information and the associated responsibility of investigators to safeguard that private information from unauthorized access.[44] Stated differently, the federal regulatory system, including the use of IRBs as an oversight mechanism, requires consideration of, and protection of research subjects from, three core risks or concerns: (1) unconsented research, (2) excessive or inappropriate risk, and (3) disclosure of confidential information (primarily health related information). The satisfaction of one factor does not eliminate the need to satisfy the other factors.

The extent to which IFs comprise risks of concern to IRBs has been the topic of much debate. As explained by Wolf et al.:

> For a research participant recruited as a normal control, discovery of an IF suggesting pathology may trigger anxiety, burdens, and the costs of further evaluation to verify or rule out a clinical problem. Even research participants with known pathology risk discovery of an unrelated IF, triggering the same. . .. [S]ome IFs will lead to

41. 45 C.F.R. § 46.111 (2011); 21 C.F.R. § 56.111 (2011).

42. 45 C.F.R. § 46.116(a)(8) (2011); 21 C.F.R. § 50.25(a)(8) (2011). There are some complex withdrawal issues associated with implanted medical devices that are not relevant to this discussion.

43. *Institutional Review Board Guidebook, Chapter III: Basic IRB Review*, DEP'T OF HEALTH AND HUMAN SERVICES, http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm#e1 (last updated 1993).

44. *Id*.

> diagnoses of clinical importance. . . For such a research participant, taking part in the study imposes both the risk of discovering an IF and potential benefit of discovering serious pathology in time to intervene. [45]

Proponents of including IFs as a category of risk to subjects argue that minimizing risks and reasonably balancing risks and benefits requires that investigators and IRBs evaluate whether: (1) a research protocol has the potential to produce IFs of clinical significance to subjects; (2) whether the protocol provides adequate procedures for addressing when and how IFs will be disclosed to subjects; and (3) whether informed consent documents adequately inform subjects about the risks and benefits of IFs, as well as whether and when they can expect IF disclosures.[46] Pursuant to this analysis, several commentators, including groups such as the National Bioethics Advisory Commission, National Institute of Health's (NIH) National Heart, Lung, and Blood Institute, and the Centers for Disease Control and Prevention have put forth recommendations for investigators and IRBs on how to identify and evaluate the adequacy of plans to address IFs arising from research.[47]

Quite importantly, these recommendations have focused almost exclusively on IFs arising in the course of primary research in which IRB review and informed consent are de facto requirements under both federal and state law.[48] Secondary research adds further complexity to issues of IF disclosure and informed consent given that the research being performed may well not even be conceived of at the time that consent is obtained. However, these analyses have not generally been applied to biobank research entities including collection sites, biobanks themselves, and secondary researchers using archived specimens and DNA data from biobanks for several reasons.

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45. Susan M. Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendation*, 36 J. LAW MED. ETHICS, 219, 227 (2008).

46. 1 NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 9, at 72.

47. *Id.*; Laura M. Beskow et al., *Informed Consent for Population-Based Research Involving Genetics*, 286 JAMA 2315, 2320 (2001); Robert R. Fabsitz et al., *Ethical and Practical Guidelines for Reporting Genetic Research Results to Study Participants: Updated Guidelines from a National Heart, Lung, and Blood Institute Working Group*, 3 CIRCULATION: CARDIOVASCULAR GENETICS 574 (2010), *available at* http://circgenetics.ahajournals.org/content/3/6/574.long; see Consensus Report, *supra* note 1, at Figure 5 for a full roster of recommendations on returning IFs.

48. 45 C.F.R. § 46.109, 46.116 (2011).

First, the Common Rule and FDA rules only apply to instances of human subjects *research*.[49] In the context of primary research, the collection of specimens and data is specifically for the purposes of the research in question and involves direct contact with human subjects, easily bringing collection activities under the gambit of requirements for informed consent and IRB review. In the context of the biobank research system, however, specimens and data may be initially collected for non-research purposes, such as when physicians obtain biological materials (e.g., blood or tissue samples) or health information in the course of clinical diagnosis or treatment.[50] Neither the Common Rule nor the FDA rules apply to such clinical collections at the time of collection. The application of the Common Rule and similar FDA requirements to the subsequent secondary use, including, for example, situations in which the non-regulated collected specimens or data are subsequently sent to a biobank or used for secondary research, is unclear. Even if the initial collection of biobanked specimens and data is research purposed (i.e., collected for primary research), current federal regulations may not (and, most often, do not) require primary researchers to obtain IRB review or informed consent for any downstream secondary research not yet conceived of that might use the collected specimens or data.[51] Those obligations, if they arise, will fall on the secondary researcher once he develops his research protocol. Furthermore, aggregation and archiving of specimens and data are not in and of themselves considered to be research activities under the Common Rule and FDA regulations.[52] Consequently, under this view, biobanks do not need IRB

49. 45 C.F.R. pts. 46, 50, 56 (2011).

50. *See, e.g.*, *NUgene*, NORTHWESTERN UNIVERSITY, https://www.nugene.org/ (last updated Oct 5, 2010) (Northwestern University NUgene biobank that "collects and stores genetic (DNA) samples along with associated healthcare information from patients of Northwestern-affiliated hospitals and clinics.").

51. The applicability of the Common Rule and FDA requirements to secondary research has been debated with differing views. While we may conclude that certain of these federal requirements are applicable to secondary research, that analysis is outside of the scope of this article. We instead focus on state law requirements.

52. *Cf.* U.S. DEP'T OF HEALTH AND HUMAN SERVS., OHRP - GUIDANCE ON RESEARCH INVOLVING CODED PRIVATE INFORMATION OR BIOLOGICAL SPECIMENS (2004) [herinafter OHRP GUIDANCE] (providing guidance as to when use of human specimens is or is not considered research).

approval or informed consent to engage in these activities.

Second, where biobanks and secondary researchers are engaged in research, these research activities often are viewed as falling outside the scope of the Common Rule or as qualifying for categorical exemptions to Common Rule requirements for IRB review and informed consent. The Common Rule definition of human subject is "a living individual about whom an investigator . . . conducting research obtains (1) [d]ata through intervention or interaction with the individual, or (2) [i]dentifiable private information."[53] The Common Rule further clarifies that private information "must be individually identifiable" such that "the identity of the subject is or may readily be ascertained by the investigator or associated with the information."[54] By contrast, the FDA rules define a human subject as "an individual [either healthy or a patient] who is or becomes a participant in research, either as a recipient of the test article or as a control"[55] without consideration for direct interaction or identifiability of information by the investigator. Thus, while the FDA rules do not allow for waiver of IRB requirements based on the identifiability of specimens and data,[56] the (current) Common Rule does include certain exclusions and exemptions that apply to a large portion of biobank research activities.

Guidance from the Office of Human Research Protections (OHRP) provides that research involving deidentified specimens or data that were either not collected for the purposes of the research in question[57] or obtained from another institute is not human subjects research at all and is excluded altogether from the Common Rule's jurisdiction.[58] The Common

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53. 45 C.F.R. § 46.102(f) (2011).

54. *Id.*

55. 21 C.F.R. § 50.25 (2011).

56. FDA does, however, allow for waiver of informed consent requirements in certain circumstances. CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, GUIDANCE ON INFORMED CONSENT FOR IN VITRO DIAGNOSTIC DEVICE STUDIES USING LEFTOVER HUMAN SPECIMENS THAT ARE NOT INDIVIDUALLY IDENTIFIABLE (2006) (providing notice that the FDA "intends to exercise enforcement discretion" when, inter alia, "[t]he study uses leftover specimens"; "[t]he specimens are not individually identifiable"; "[t]he specimens are provided to the investigator(s) without identifiers"; "[t]he individuals caring for the patients are different from, and do not share information [with those] conducting the investigation"; and "[t]he study has been reviewed by an IRB . . . .").

57. OHRP GUIDANCE, *supra* note 52.

58. *Id.*

Rule itself also includes a categorical exemption from IRB review and informed consent requirements for "[r]esearch involving the collection or study of existing data . . . pathological specimens, or diagnostic specimens, if . . . the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."[59] Consequently, biobanks and secondary researchers can arguably avoid the Common Rule-based IRB review and informed consent requirements by either obtaining specimens or data that are already deidentified or by separating such specimens and data from their identifying information prior to commencing research. Furthermore, even in some instances where secondary research involves existing but identifiable specimens and data, federal, Common Rule-based requirements for informed consent may potentially be satisfied if the original collection site obtained general consent for future research or if the original consent is found to be compatible with the secondary research use.[60]

A third source of regulatory authority pertinent to the biobank research system is HIPAA, which applies only to "covered entities" including health care plans, health care clearinghouses, and health care providers that transfer health information in electronically.[61] HIPAA restricts how covered entities may use or disclose protected health information (PHI), including information linked to biological samples[62] that

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59. 45 CFR 46.101(b)(4) (2011). A key note here is that, unlike the excluded categories of non-human subjects research defined by OHRP, this exempt category of research is subject to the final authority of DHHS and agency heads for determining whether the requirements for the exemption are in fact satisfied. 45 CFR 46.01(c) & (d) (2011).

60. DEP'T OF HEALTH AND HUMAN SERVS., FAQS, TERMS AND RECOMMENDATIONS ON INFORMED CONSENT AND RESEARCH USE OF BIOSPECIMENS: THE SECRETARY'S ADVISORY COMM. ON HUMAN RESEARCH PROTECTIONS (2010), *available at* http://www.hhs.gov/ohrp/sachrp/commsec/attachmentdfaq'stermsandrecommendations.pdf ("The determination of whether a proposed secondary research use is compatible with the original consent will be context-specific based on a range of considerations. If the original consent form specifically prohibited the proposed research activity, it is presumed the research is not allowable. If the consent does not prohibit the proposed use, IRBs should consider several questions to determine compatibility . . . .").

61. 45 C.F.R. § 164.104(a) (2011).

62. 45 C.F.R. § 164.502 (2011). HIPAA does not otherwise bind to biological samples. DEP'T OF HEALTH & HUMAN SERVS., RESEARCH REPOSITORIES, DATABASES, AND THE HIPAA PRIVACY RULE 11 (2004),

pertains to an individual's current, past, or future health or health care and is either individually identifiable or provides a reasonable basis for individual re-identification.[63]

HIPAA may apply to a range of biobank research entities, including clinical collection sites that provide health care at the time of collection and electronically transmit PHI to biobanks,[64] biobanks located at academic health centers or at hospitals,[65] and secondary researchers receiving PHI from biobanks that are covered entities.[66] Because HIPAA defines PHI as individually identifiable, it does not regulate covered entities from using or disclosing deidentified health information as long as an expert using "generally accepted statistical and scientific principles and methods" can attest there is a "very small" risk of re-identification, or if the health information is stripped of eighteen specific identifiers provided under the regulation.[67] Covered entities may retain the code linking deidentified information to their identified source, but are prohibited under HIPAA from using or disclosing the code.[68] If the code is used by a covered entity for re-identification, the information is reinstated as PHI and the covered entity is again subject to HIPAA requirements.[69] In order to use or disclose PHI for research, a covered entity must first obtain authorization from the individual to whom the PHI is linked.[70] This individual

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available at http://privacyryleandresearch.nih.gov/pdf/research_repositories_final.pdf.

63. 45 C.F.R. § 160.103 (2011).

64. DEP'T OF HEALTH & HUMAN SERVICES, RESEARCH REPOSITORIES, DATABASES, AND THE HIPAA PRIVACY RULE, *supra* note 62, at 1.

65. *Id*. ("Researchers are not themselves covered entities, unless they are also health care providers and engage in any of the covered electronic transactions. If, however, researchers are employees or other workforce members of a covered entity (e.g., a covered hospital or health insurer), they may have to comply with that entity's HIPAA privacy policies and procedures.").

66. *Id.*

67. 45 C.F.R. § 164.514(b) (2011).

68. 45 C.F.R. § 164.514(c). Under the Public Health Service Act, DHHS also has authority to issue certificates of confidentiality to any investigator conducting a study that requires IRB approval under the Common Rule when the study involves the identifiable information. However, while HIPAA prohibits covered entities from disclosing identifying information, certificates of confidentiality only provide investigators the legal right to refuse disclosure. They do not prohibit investigators from making voluntary disclosures. 42 U.S.C. § 241 (2006).

69. 45 C.F.R. § 164.502(d)(2) (2011).

70. 45 C.F.R. § 164.508(a)(1) (2011).

authorization can be combined with informed consent required under the Common Rule or FDA regulations[71] and must address the risk to the individual's privacy posed by the authorized use or disclosure.[72]

An important note is that HIPAA does not allow for general authorizations for future use and disclosure and, instead, always requires study-specific authorizations.[73] As with the Common Rule, HIPAA also contains certain provisions that allow covered researchers to bypass its requirements. First, HIPAA includes a provision that allows covered entities to use or disclose identifiable PHI for research without individual authorization through the obtainment of a waiver of authorization from an IRB or institutional Privacy Board[74] based on the satisfaction of three criteria: (1) the research poses no more than minimal risk to the privacy of individuals, (2) the research could not practicably be conducted without the waiver, and (3) the research could not be practicably conducted without using PHI.[75] Covered researchers can also avoid the need for individual authorizations by using a "limited data set"[76] that contains certain demographic information about individuals in conjunction with a data use agreement that identifies permitted uses and disclosures of that information[77] and bars the recipient of the limited-data set from identifying the information or contacting the individuals to whom the

71. 45 C.F.R. § 164.508(b)(3)(i).

72. DEP'T OF HEALTH & HUMAN SERVICES, PROTECTING PERSONAL HEALTH INFORMATION IN RESEARCH: UNDERSTANDING THE HIPAA PRIVACY RULE 11 (Apr. 14, 2003), *available at* http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf ("An authorization differs from an informed consent in that an Authorization focuses on privacy risks and states how, why, and to whom the PHI will be used and/or disclosed for research. An informed consent, on the other hand, provides research subjects with a description of the study, its anticipated risks and/or benefits, and a description of how the confidentiality of records will be protected, among other things.").

73. 45 C.F.R. § 164.508(b)(3); *see also* DEP'T OF HEALTH AND HUMAN SERVS., FAQS, TERMS AND RECOMMENDATIONS ON INFORMED CONSENT AND RESEARCH USE OF BIOSPECIMENS: THE SECRETARY'S ADVISORY COMM. ON HUMAN RESEARCH PROTECTIONS, *supra* note 60 (indicating DHHS' interpretation of HIPAA as requiring study-specific authorizations.).

74. 45 C.F.R. § 164.512(i)(1)(1) (2011).

75. 45 C.F.R. § 164.512(i)(2)(ii).

76. 45 C.F.R. § 164.514(e) (2011).

77. 45 C.F.R. § 164.514(e)(4)(ii)(A) (2011).

information pertains.[78]

The combined effect of these regulatory regimes is that biobank research entities can arguably avoid most if not all federal requirements for IRB review, informed consent, and individual authorization by de-identifying their specimens and data. The results with respect to IF disclosures are three-fold. First, there may be no opportunity for an IRB to evaluate whether the secondary research poses any risks or benefits associated with IFs. Second, disclosures of IFs may be impracticable or impossible depending on the extent to which re-identification is technically possible or legally allowable. Finally, even when disclosures of IFs remain a possibility, the very act of considering them for disclosure or identifying their sources may trigger an uncertain and complex web of regulatory requirements that includes certain preconditions (i.e., informed consent, IRB review, and individual authorization) to research that the researchers did not and, indeed, were not required to satisfy before they began doing the research.

Proposed changes to this regulatory landscape as articulated in the ANPRM address some of the challenges raised by the biobank research system, but have an overall effect that further frustrates disclosures of IFs. In contrast to the claims stated above that IFs pose physical, psychological, and economic risks and benefits to human subjects, the ANPRM states that:

> [I]ncreasing use of genetic information, existing (i.e., stored) biospecimens, medical records, and administrative claims data in research has changed the nature of the risks and benefits of research participation. Risks related to these types of research are not physical but informational (e.g., resulting from the unauthorized release of information about subjects).[79]

As such, the ANPRM argues for several proposed changes to current Common Rule requirements to address these information risks. The first set of changes are definitional and involve the adoption of HIPAA's rigorous definitions for identifiable information, deidentified information, and limited-data sets in place of the Common Rules current, less stringent definition for individually identifiable information. The ANPRM provides that, under these more rigorous definitions, "all research involving the primary collection of biospecimens

78. 45 C.F.R. § 164.514(e)(4)(ii)(C)(5).

79. *ANPRM*, *supra* note 20, at 44,513–14.

as well as storage and secondary analysis of existing biospecimens [would be categorized] as research involving identifiable information."[80] This change stems from the ANPRM's position that "[r]egardless of what information is removed, it is possible to extract DNA from a biospecimen itself and potentially link it to otherwise available data to identify individuals."[81]

For researchers using deidentified information or limited-data sets, the ANPRM argues that mandatory data security standards, including provisions that "strictly [prohibit researchers] from attempting to re-identify the subjects of the information,"[82] can provide better protection against informational risks and, thus, should replace IRB review of such concerns.[83] Citing the increase reliance of investigators on third-party experts to remove identifiers instead of recording information in an un-identifiable manner themselves, the ANPRM also argues that "data could be considered deidentified or in a limited data set form even if investigators see the identification but do not record them in the permanent research file."[84]

The second set of changes pertains to informed consent. As stated by the ANPRM, under these revised rules "the allowable current practice of telling the subjects, during the initial research consent, that the data they are providing will be used for one purpose, and then stripping identifiers, allowing it to be used for a new purpose to which the subject never consented, would not be allowed."[85] The ANPRM further provides that these consent requirements can be satisfied in most cases at the time of the initial collection of specimens/data by having subjects sign a "brief general consent form allowing for broad, future research" or allowing the subject to reject future research. In instances requiring more specific consent, such as cell line or reproductive research, this initial consent form could provide check-boxes allowing subjects to opt in or out of

80. *Id*. at 44,525.
81. *Id*.
82. *Id*. at 44,526.
83. *Id*. Note that this portion of the ANPRM did not address the return of IFs.
84. *Id*.
85. *Id*. at 44,519.

these particular types of research.[86]

The proposed rules would require informed consent for all biospecimens and identifiable data regardless of whether originally collected for research or non-research purposes, but allow for that consent to be acquired at the time of initial collection. For research on limited data sets and deidentified data, informed consent would be required unless the data was originally collected for a non-research purpose. Perhaps paradoxically, the approach proposed in the ANPRM provides less protection for those individuals who have the least knowledge that their biospecimens or health information will be used in research. It would seem that this category of "contributors" are entitled to at least some advance knowledge and ability to consent (or to withhold consent) before research is commenced using their specimens and information. Such consent as is proposed by the ANPRM could also be obtained at the time of the initial collection. The ANPRM states that these informed consent requirements would only apply prospectively to specimens/data collected after the adoption of the new rules.

The third set of changes pertains to the nature of IRB review and the categories of research exempt from IRB review. While the current Common Rule provides that "[r]esearch involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, . . . if the information is recorded by the investigator in a manner that subjects cannot be identified" is exempt from all requirements, these research studies would have to comply with new mandatory federal data security standards under the amended Common Rule. The ANPRM frames this change as "moving away from the concept of exempt [research studies]" to a category of research studies "excused" from IRB review. [87] Because this shift increases protections for subjects beyond what is provided in the status quo, the ANPRM argues that the "excused" category can be expanded to include more types of studies than in the current "exempt" category.[88]

Thus, the ANPRM proposes that the current exemption for research on pre-existing specimen/data be amended "to clarify that the word 'existing' means collected for purposes other than

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86. Note, however, that the ANPRM states that "[p]articipation in a research study (such as a clinical trial) could not be conditioned on agreeing to allow future open-ended research using a biospecimen." *Id*. at 44,520.

87. *Id*. at 44,518.

88. *Id*.

the proposed research and not that all the data or biospecimens need exist that the time the study commenced."[89] Furthermore, the ANPRM proposes that the current limitation on investigators recording identifying information be eliminated "unless there are plans to provide individual results back to the subjects," in which case the study would be ineligible for excused status altogether.[90]

Research that does not qualify as excused under the amended Common Rule would still require review by a fully convened IRB. However, with the adoption of mandatory data security standards, IRBs would only assess the ethical dimensions of these research protocols, but would no longer be responsible for assessing their information risks.[91] Furthermore, while the current Common Rule requires IRBs to provide ongoing review of such research studies as a default, the ANPRM proposes that "[w]here the remaining activities in a study are limited to . . . data analysis (even if identifiers are retained) . . . , the default would be that no continuing review by an IRB would be required" unless the IRB decides that on-going review is necessary.[92]

To facilitate tracking and auditing of excused studies, researchers would be required to register these studies with an IRB using a brief (one page) form.[93] This form, the ANPRM contends, would allow institutions to identify those rare instances where an excused study might require expedited or full IRB review.[94]

Overall, the federal regulatory system provides substantial privacy protections for public disclosures of confidential personal health information, but limited research subject/contributor/source protection. In particular, the federal regulatory system provides limited informed consent requirements, which are particularly noticeable in situations in

89. *Id*. at 44,519.
90. *Id*.
91. *Id*. at 44,516.
92. *Id*.
93. *Id*. at 44,520.
94. *Id*. (discussing how the implementation of the brief registration form would allow researchers to begin their work after filing and certain filings that did not meet the requirement for being "'excused"' would be subjected to "comprehensive administrative review," which would prevent each filer from having to go through this extensive process).

which the biospecimen or information is collected outside of a research context.[95] The federal system also provides limited guidance on when and how to return IFs to human sources.[96] The role and responsibilities of secondary research is addressed only in passing.[97]

This federal structure makes biobank based research more economical and efficient for the researchers but may well not address all of the ethical, medical, or legal rights or concerns of the human sources.

II. REGULATORY FAILURE OF BIOBANK RESEARCH OVERSIGHT

The issue of IF disclosures comprises only a subset of rights and interests of human sources that are implicated by biobank research. Indeed, the debate over IFs seems in many respects to presuppose that federal regulations adequately address many of the more fundamental issues raised by biobank research that we believe are either inadequately resolved or wholly unsettled as legal and ethical matters. These issues include: the status of human sources of biological samples and genetic information as human research subjects; the rights of human sources to decide whether and how their samples and information can be used by others with or without consent; the duties owed to human sources by those who collect, store, and conducting research on their samples and information; and the effect of deidentification on these various

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95. *See id.* at 44,523 ("Critics of the existing rules [for informed consent] have observed that the current requirements for informed consent for future research with pre-existing data and biospecimens are confusing and consume substantial amounts of researchers" and IRBs" time and resources. Under the Common Rule and the HIPAA Privacy Rule, if identifiers are removed, specimens and data that have been collected for purposes other than the proposed research can be used without any requirement for informed consent or a HIPAA authorization.").

96. *See, e.g.*, *id.* at 44,520 (seeking advice on providing human research subjects with more protection and asking "Currently some IRBs make determinations regarding whether clinical results should be returned to study participants. How should such determinations be made if the study now fits in the Excused category? Can standard algorithms be developed for when test results should be provided to participants and when they should not (e.g., if they can be clinically interpreted, they must be given to the participants?")).

97. *See* 45 C.F.R. § 46.101(b)(4) (2012) ("Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.").

rights and duties.

It is our contention that these fundamental issues are not only inadequately handled by the current federal regulatory regime, but also that the observable practices of the biobank research system that are currently allowable under some interpretations of federal regulations as well as the recent actions of the federal regulatory authorities, including the ANPRM, are indicative of a potential regulatory failure in which the very rights that are supposed to be protected by federal regulations are instead being undermined. It is not our intention to assign blame for this regulatory failure, but to bring attention to what we see as a rapidly emerging dissonance between the letter of the federal law and bioethical concerns, state oversight of research, human source expectations, and the spirit with which the federal oversight system was initially created.

Federal human subjects research regulations were developed in large part because of well documented failures of researchers and oversight systems, both within the United States and outside of the United States, to protect human subjects.[98] The rights of research subjects and the duties of researchers were not as historically and widely addressed by principles of common law as those that exist in the context of the physician-patient relationship.[99] The Twentieth Century saw the rise of structured, complex human subject research projects and the corresponding rise of the academic, government, and private research industry.[100] Much of this

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98. *See, e.g.,* U.S. DEP'T OF HEALTH AND HUMAN SERVS., PROTECTION OF HUMAN SUBJECTS IN RESEARCH FUNDED OR REGULATED BY U.S. GOVERNMENT: HOW TODAY'S RULES PROHIBIT ETHICAL ABUSES IN HUMAN SUBJECTS RESEARCH (2010), *available at* http://www.hhs.gov/1946inoculationstudy/information_on_protection_of_human_subjects_in_research.pdf (detailing the history and development of federal human subjects research protections); *see also* Donald H.J. Hermann, *Lessons Taught By Miss Evers' Boys: The Inadequacy Of Benevolence And The Need For Legal Protection Of Human Subjects In Medical Research*, 15 J. L. & HEALTH 147,147 (2000) (summarizing the Tuskegee Syphilis Study).

99. *See* Wolf et al., *supra* note 4, at 363 ("Clinicians owe patients a duty of care, which if breached, exposes clinicians to malpractice liability. Researchers, on the other hand, have until very recently been held to owe research participants few, if any, duties of clinical care enforceable in tort or contract law.") (footnotes omitted).

100. *See generally* Adam H. Laughton, *Somewhere to Run, Somewhere to Hide?: International Regulation of Human Subject Experimentation*, 18 DUKE

research was federally funded, federally directed, or federally mandated.[101] There was a parallel rise in the rights of patients and human research subjects to control their care or participation in research and their rights to information. Federal regulatory systems were created to address research conduct, particularly when conducted using federal funds.[102] These federal regulatory systems did not, however, replace other common law, statutory, or regulatory protections at the state, federal, or international levels.[103]

As such, federal regulations governing human subjects research can best be regarded as establishing the minimum rights and duties arising from the research context. Research subjects may well be afforded more protections under common law principles of contracts and any additional rights they have under state or common law. Indeed, the very language of the Common Rule and similar FDA requires for informed consent provides that:

> No informed consent, whether oral or written, may include any exculpatory language through which the [research] subject . . . is made to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.[104]

The legal rights referenced in the Common Rule include rights to bring product liability suits and to assert medical malpractice or privacy violations—many of which are state law based.[105]

Similarly, the decentralization approach of using IRBs as an additional oversight system to evaluate and approve

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J. COMP. & INT'L L. 181, 181–91 (discussing the historical development of human research and corresponding regulations).

101. *See, e.g.*, *id.* at 185–87 (highlighting several controversial 20th Century American research studies conducted with human subjects and the U.S. government's role in those studies).

102. *See id.* at 187 ("The revelation of the Tuskegee experiments resulted in the passage of the National Research Act in 1974, which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1979, the Commission published the Belmont Report which identified 'basic ethical principles' and applications of those principles that were relevant to human subject research. The recommendations of the Belmont Report were adopted by the Department of Health and Human Services and many other federal agencies and incorporated into their regulations. These recommendations evolved into what is currently known as the 'Common Rule' for human research protection.") (footnotes omitted).

103. 45 C.F.R. § 46.101(e)–(g) (2011).

104. 45 C.F.R. § 46.116 (2011); 21 C.F.R. § 50.20 (2011).

105. *Id.*

research protocols on the basis of minimization and reasonability of risk, adequacy of informed consent, protection of privacy, and other standards set forth in the Common Rule and similar FDA rules is designed to allow for additional consideration of state and institutional requirements beyond those established under federal law.[106]

The potential regulatory failure that we identify is one in which these federal regulations are being approached as the ceiling for rights and duties rather than as the floor. Furthermore, through some process that we do not attempt to diagnose, these federal regulations appear to be increasingly moving in the direction of providing fewer and fewer protections for research subjects, especially in the area of research using genetic specimens and data. This is evidenced both by the relaxation of informed consent and IRB review requirements proposed in the recent ANPRM and by recent draft guidance from OHRP and FDA on exculpatory language in informed consent which states that:

> [A] subject's waiver of any rights he or she may have with respect to a biospecimen obtained by investigators for research purposes would not be exculpatory because it does not have the effect of freeing the investigator, sponsor, institution, or others involved in the research from malpractice, negligence, blame, fault, or guilt.[107]

While the explanatory discussion of this draft guidance states that "[s]uch language may be considered an acceptable way to accurately inform subjects that they will not be receiving any financial compensation, now or in the future, for the use of those biospecimens,"[108] the examples of acceptable informed consent language listed in the draft guidance go far beyond waivers of financial interest and include "I voluntarily and freely donate any and all blood, urine, and tissue samples to the [name of research institution] and hereby relinquish all property rights, title, and interest I may have in those samples"[109] and "[b]y consenting to participate in this research, I give up any property rights I may have in bodily fluids or

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106. 45 C.F.R. § 46.109(a)–(b) (2011); 21 C.F.R. § 56.109(a)–(b) (2011).

107. OFFICE FOR HUMAN RESEARCH PROT. & FOOD AND DRUG ADMIN., GUIDANCE ON EXCULPATORY LANGUAGE IN INFORMED CONSENT 2 (draft guidance) (2011), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM271036.pdf.

108. *Id.* at 2–3.

109. *Id.* at 3.

tissue samples collected during this research."[110]

The most significant concern with this situation—one which, as far as we know, has not previously been identified—is that the biobank research system, still nascent in most regards, is looking to these waning protections as unilaterally establishing the maximum or totality of the duties and standards of care by which it can operate.[111] This concern is no better illustrated than with the issue of IFs arising from research using biobanked specimens and data.

While the issue of IFs arising from the biobank research system is fairly new, many commentators have discussed in recent years the issue of what to do with IFs arising in the course of primary research. In 2008, Wolf et al. provided a comprehensive analysis of legal and ethical sources establishing researchers' duties to consider and manage IFs arising in the course of their research. Looking at ethical sources, the authors found support for such duties based on notions of beneficence and reciprocity between researchers and research participants,[112] concern for participants' welfare,[113] and respect for participants' autonomy.[114] Looking at the source of duties arising under federal regulations, the authors argue that in order to satisfy their regulatory mandate to minimize risks to human subjects and maintain reasonable balance

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110. *Id.*

111. Drabiak-Syed raises a related point, stating:

> Despite some prescriptive requirements [provided under the Common Rule and HIPAA for the collection, storage, and research use of biospecimens from biobanks], the federal law fails to adequately protect individuals' interest from unwanted collection and use of their tissues for genetic research as a result of ambiguity and liming the applicability of federal regulation to situations of direct identifiability. Several state legislatures have magnified these loopholes in federal regulation, codifying sweeping unregulated exceptions to promote medical and scientific research advancement.

Drabiak-Syed, *supra* note 23, at 229.

112. Wolf et al., *supra* note 4, at 365 ("Relying on the ethical duty of reciprocity suggests that researchers 'incur obligations to help or benefit [research participants] in part because [researchers] have received or will receive assistance from [those participants]'") (footnotes omitted).

113. *Id.* at 365–66 (citing arguments that research participants trust researchers to observe abnormal findings of significance and that researchers' discretion to share such information is key to participants' well-beings given the vulnerable position of participants).

114. *Id.* at 366 ("Respect for persons includes a respect for participants' self-determination and consequent need for information relevant to their health and well-being . . . .").

between risks and benefits, researchers and IRBs must address how IFs will be handled.[115] They state:

> Whenever individuals participate in genetic, genomic, or imaging research, they risk discovery of an IF. Finding out about an IF may impose psychological burden, the financial burden of follow-up assessment, and risk of bad sequelae from the follow-up tests. . . . Yet there is also a risk that researchers will fail to notice an IF of high clinical importance, and research participants will thus lose a chance to avoid or ameliorate serious clinical consequences. . . . The regulatory duty to minimize all of these risks suggests the obligation to create a solid plan to address IFs in the course of research.[116]

Wolf et al. also argue that Common Rule requirements for informed consent disclosures, including disclosures of foreseeable benefits and risks and disclosures of findings developed over the course of research that may affect participants' choice to continue their participation, all point toward IRBs requiring that IFs be discussed in the informed consent process.[117] Finally, looking at sources of researchers' duties arising under state common law, Wolf et al. find that there may be sufficient basis to regard a failure to disclosure an IF as a breach of the duty of care owed by a researcher to a research subject.[118] As previously mentioned, based on this and other commentary, several organizations have produced recommendations for the management of IFs arising in the course of research.[119]

So why then, in light of all the compelling arguments and support in favor of addressing IFs arising from primary research as part of researchers' ethical and legal duties, is the disclosure of IFs from secondary research being disincentivized by federal regulations? The answer may be found in the following illustrative hypothetical offered by Ellen Wright Clayton for how an IF disclosure from genetic research using archived DNA might play out:

> You were a patient at Hospital A several years ago when you were suffering from disease X, which has long since resolved. You have just arrived home from a long day's work when the phone rings. When you

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115. *Id.* at 367.

116. *Id.*

117. *Id.*

118. *See generally id.* at 369–73 (discussing cases in which "[r]esearch subjects have . . . claimed that researchers have duties [of care] arising under state common law doctrines grounded in tort, property, or contract.") (footnotes omitted).

119. *See supra* text accompanying note 47.

> answer, a soothing voice says, "I am a scientist at Research Institute B two time zones away. I was examining your DNA and found a variant associated with Disease Y that may be really important for your health. Do you want to know about it?" If the scientist were particularly thoughtful, she might ask, "Can you come here for genetic counseling?" You wonder, What is DNA? How did she get mine? What is a variant? What is Disease Y? What is genetic counseling? Who is going to pay for me to go to Research Institution B? Most importantly, you think, What choice do I have?[120]

According to Clayton, this scenario highlights the central problems with disclosing IFs that arise from secondary research: (1) that the archiving, sharing, and research use of DNA is so pervasive and complex that the human sources from whom DNA samples are taken may not understand when, how, and for what end their DNA can be archived, shared, and used;[121] (2) that, because of this lack of understanding, sources are often unaware that their samples are being used for secondary research and may be caught off guard by disclosures of IFs; and (3) that researchers may lack the knowledge to adequately identify, interpret, and explain the significance of IFs arising from their research. Given these problems, Clayton argues that it may be appropriate to offer sources the opportunity to give informed consent to IF disclosures but that, absent such informed consent, "a general policy of offering incidental findings to unsuspecting people who had not previously thought about the issue just does not seem right."[122]

We bear no cynicism toward this position that unexpected disclosures of IFs can pose significant psychological harms to unsuspecting sources and that informed consent for such disclosures may very well be required by standards for ethical research. The concern of biobanks and secondary researchers for the welfare of their human sources is tested, however, by four notable observations.

The first observation is paradigmatic in nature—while researchers express concerns about the devastating psychological harms that a source might face when unexpectedly finding out that they may have a problem, they

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120. Ellen Wright Clayton, *Incidental Findings in Genetics Research Using Archived DNA*, 36 J.L. MED. & ETHICS 286, 286 (2008).

121. This concern seems based on a view that the average patient is incapable of understanding enough about genetic research to make any informed choice either before the research is conducted or after the results are available. This arguably paternalistic view was also the basis, discarded many years ago, for not disclosing drug risks to patients.

122. Clayton, *supra* note 120, at 290–91.

seldom discuss the devastating physical harms that a source might face if they are not informed about a problem they could avoid or mitigate had they been told of it. For whatever reasons, the potential psychological risks of disclosure are elevated over the medical, clinical, and physical risks posed by non-disclosure.

While providing informed consent for disclosures could help address this issue, the effectiveness of this approach is curtailed by the second observation—in lieu of providing informed consent for disclosures, some biobanks (including BioVu, the biobank at Clayton's own Vanderbilt University) are opting to use methods such as irreversible deidentification to make disclosure of IFs impossible in the first place.[123] This approach eliminates the psychological risks of potential disclosure by also eliminating the benefits of disclosure of medically critical IFs. In many ways, this is again an elevation of psychological factors related to disclosure above the other risks, benefits, and rights related to the disclosure of critical clinical information, as well as rights to know and control how one's biomaterial is being used.

Third, a disclosure of an IF necessarily also requires disclosure of the fact, subject, and scope of the secondary research that gave rise to the IF. Such disclosure can expose the researcher to criticism and objections. Some human sources may well not want any undisclosed or unconsented research to be conducted using their biospecimens or DNA data in the first place.[124] Other human sources may have ethical, religious, or other personal objections to having their biospecimens or data used in certain types of research.[125] For example, some human sources might object to the use of their biospecimens or data for research into questions of any genetic basis for sexual

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123. *See generally* Khaled El Emam, *Methods for the De-Identification of Electronic Health Records for Genomic Research*, 3 GENOME MED. (2011), *available at* http://genomemedicine.com/content/pdf/gm239.pdf (discussing various de-identification methods in use) and highlighting, specifically, the de-identification process used by Vanderbilt University's BioVU).

124. *See* R.M. Sade, *Research on Stored Biological Samples is Still Research*, 162 ARCHIVES OF INTERNAL MED. 1439, 1440 (2002) ("There should be no doubt about what is at stake in developing policy for the use of stored samples: the fundamental right to decide whether and how one's body and its parts will be used in research.").

125. *See id.* (discussing the broad range of reasons for which a person may not want to participate in research studies).

orientation or for the development of certain reproductive or contraceptive technologies. Others may object to the use of their biospecimens or data for research into ethnic or racial differences in the safety or effectiveness of certain drugs or medical therapies.[126]

Researchers may well wish to avoid facing such potential controversy. Along the same lines, informing the human source of the research may result in the human source explicitly withdrawing consent or affirmatively requesting that he be removed from the research, thus putting the research project (and the researcher's role in the research) at risk.[127] In fact, those who oppose study-specific informed consent often argue that allowing human sources to withhold or withdraw consent could affect the number of available samples on which to conduct research or introduce some selection bias.[128] And yet, at the same time, these opponents to study-specific informed consent also cite to studies that purportedly demonstrate that most individuals do not have any objections to the unlimited use of their biospecimens in future research without their consent.[129] This raises the poignant question: If most people

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126. BiDil is the classic example of a drug with an ethnicity based FDA approval. There are obvious social, cultural, and ethical issues with race or ethnicity based products. *See generally* Susan M. Reverby, *"Special Treatment": BiDil, Tuskegee, And the Logic of Race*, 33 J. L. MED. & ETHICS 478 (2008) (discussing the issues surrounding BiDil through a racially-orientated lens).

127. *See, e.g.*, Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 850–51 (2001) ("There is always a potential substantial conflict of interest on the part of researchers as between them and the human subjects used in their research. If participants in the study withdraw from the research study prior to its completion, then the results of the study could be rendered meaningless. There is thus an inherent reason for not conveying information to subjects as it arises, that might cause the subjects to leave the research project. That conflict dictates a stronger reason for full and continuous disclosure.").

128. *See, e.g.*, Mats G. Hansson et al., *Should Donors Be Allowed to Give Broad Consent to Future Biobank Research?*, 7 LANCET ONCOLOGY 266, 266–67 (2006) ("Since the response for collection of data (eg [sic]. sending out questionnaires or asking for renewed consent to use biobank samples obtained previously) from any large population commonly ranges between 50% and 90%, the need for renewed consent for use of biobank material would reduce the number of participants available, possibly introducing selection bias and decreasing the scientific importance of the studies.").

129. *See* Marshall B. Kapp, *Ethical and Legal Issues in Research Involving Human Subjects: Do You Want a Piece of Me?*, 59 J. CLINICAL PATHOLOGY 335, 337 (2006) ("Other surveys demonstrate that most individuals who have had tissue removed for other purposes have no objection to the unlimited use of excess tissue in future research studies.").

have no problem consenting to such research, then why are researchers so concerned that not enough people will consent? Indeed, there appears to be some conflict between the interest of the researcher to avoid having to explain and obtain consent necessary to sustain their research projects and the rights of human sources to know and consent to their involvement in research. Eliminating any possibility of IF disclosures has, in many respects, also helped to eliminate this conflict, as well as the risk of controversy faced by biobanks and researchers. This scenario is frighteningly similar to the very controversies that gave rise to human subjects research protections in the first place.[130]

Finally, the fourth observation requires reading the subtext of Clayton's final and most important question posed by the hypothetical unsuspecting research participant: "What choice do I have?"[131] To start, while the question is posed in the hypothetical as "what choice do I [the research subject] have now that I know that something is wrong with me," the underlying questions seems to be "what legal rights do I [the research subject] have now that I know I have been the subject of research without my consent," as well as "what legal or ethical requirements do I [the researcher] have now that I have found something clinically wrong with the human subject." It is this concern with potential legal liability that we believe may be a driving factor for the solution proposed by some: set the bar high for when disclosures can take place and permit researchers to avoid any legal or ethical obligations by immediately and permanently destroying identifying information linking archived DNA to their human sources such that subsequent disclosure of IFs becomes impossible.

In the next section, we discuss our own illustrative hypothetical example—that which explores what we think is likely to happen as biobanks and researchers continue to operate without informed consent and continue to avoid disclosures of IFs as permitted by federal regulations.

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130. *See supra* notes 100–102 and accompanying text.
131. Clayton, *supra* note 120.

III. ENFORCEMENT AND LIMITS OF IF DISCLOSURES: WHAT HAPPENS WHEN STATES GET INVOLVED

We begin with our own version of Clayton's hypothetical from Part II:[132]

> You were a resident of the state of Red five years ago when you checked into Hospital A in the state of Blue to undergo routine surgery under the care of Dr. Physician for disease X, which has long since resolved. Unbeknownst to you, a tissue specimen taken from you in the course of your care at Hospital A is sent to Biobank B in the state of Green for archiving. Six months later, a researcher at Research Institute C two time zones away in the state of Yellow obtains your specimen from Biobank B and, in the course of research, discovers a rare genetic variant associated with malignant hyperthermia (MH), a potentially life-threatening condition triggered by exposure to certain commonly used but easily substitutable anesthetics. A year later, you move to the state of Purple, where you undergo routine surgery and have a severe reaction to the anesthesia, leaving you severely injured and impaired. In seeking to gain a better understanding of MH and how such a tragedy could befall you, you come across a research article that discuss MH as an "incidental finding." Curious about what an incidental finding is, you delve a little deeper and find the large body of literature on incidental findings arising in the course of genetic research, including several articles on how hospitals transfer their leftover specimens from patients to biobanks for use in genetic research. You try to remember if Dr. Physician or anyone at Hospital A ever talked to you about what they were going to do with your leftover specimen. You wonder, did Hospital A send my leftover specimen to a biobank for research? Did they have any right to do so without my permission? Is it possible that at some point someone conducting research on my specimen discovered that I was at risk of MH and didn't tell me? Most importantly, you wonder what are my choices?
>
> You then discover, perhaps as part of a malpractice suit, that your biosample has been transferred from institute to institute and subjected to research that screened for MH—all without your knowledge or consent. You are particularly incensed when you discover that the secondary researchers did find that you were at risk for MH and that no one told you or

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132. *See* Clayton, *supra* note 120 and accompanying text.

your physicians.

We believe that scenarios similar to this are not only likely but inevitable especially as public concern for and media coverage of issues such as genetic privacy continues to gain momentum. The "aha" moment may come when an affected individual makes a discovery in the literature such as that described in the hypothetical above, or may come when a researcher plagued with guilt over an incidental finding decides to throw protocol to the wind and blow the proverbial whistle by informing someone about a particularly important IF. It may also come to the forefront as part of other litigation or government enforcement action. Regardless of the specifics, when such scenarios arise, the affected individuals are likely seek legal counsel to assess what options for redress are available to them. In this section, we will use the hypothetical above to discuss the panoply of liability issues that such scenarios will likely raise for biobank research entities. As we proceed with our analysis, we ask the reader to bear in mind that such scenarios will play out not once or twice, but with multiplying frequency as news of early legal actions garner attention from others in similar situations. Indeed, given the scale of biobank research activities and the massive number of individuals with specimens and data currently archived in biobanks, we predict that early suits could quickly give rise to class actions. For now, however, let's continue our analysis of the hypothetical at hand.

Let us assume that the injured party in our hypothetical, who we will henceforth call Plaintiff, contacts an attorney about his situation. The attorney begins his investigation by looking at the informed consent provided to Plaintiff by Dr. Physician and Hospital A and finds no disclosure or consent pertaining to the research use of leftover specimens from surgery. The attorney next inquires as to Hospital A's practices for disposing of leftover specimens from surgical procedures. The attorney learns that Hospital A typically sends its leftover specimens to biobanks. The attorney further learns that Hospital A does not obtain informed consent from its patients prior to making such specimen transfers to biobanks. From this, the attorney forms his first question:

- Does Plaintiff have any cause of action against Dr. Physician or Hospital A related to their failure to obtain his informed consent

prior to transferring his leftover specimen to a biobank for storage?

- Does Plaintiff have any cause of action against Dr. Physician or Hospital A related to their transfer of his leftover specimen to a biobank for storage?

The attorney then obtains copies of Hospital A's material transfer agreements and discovers that Plaintiff's specimen was sent to Biobank B. Filing more discovery, the attorney obtains Biobank B's material transfer agreement transferring Plaintiff's deidentified specimen to Research Institute C for secondary research. The attorney also learns that Biobank B retains the identifying code for all its archived specimens. Here, the attorney forms his second and third questions:

- Does Plaintiff have any cause of action against Biobank B related to Biobank B's failure to obtain his informed consent prior to transferring his specimen to Research Institute C?
- Does Plaintiff have any cause of action against Biobank B related to Biobank B's storage of his specimen for secondary research?

Delving deeper into Research Institute C's activities, the attorney learns that Plaintiff's specimen was used for a research study on genetic markers for a particular type of cancer under the leadership of Dr. Investigator. The attorney further learns that the R1Y1, the genetic variant for MH, was incidentally mapped in the course of this research study. Thus, the attorney forms his fourth, fifth, and sixth questions:

- Does Plaintiff have any cause of action against Research Institute C or Dr. Investigator related to their use of his specimen for research?
- Does Plaintiff have any cause of action against Research Institute C or Dr. Investigator related to their failure to obtain his informed consent prior to commencing research on his specimen?
- Does Plaintiff have any cause of action against Research Institute C or Dr. Investigator related to their failure to inform him of the incidental R1Y1 finding?

The attorney begins looking at the types of state laws that might exist that could give rise to these potential causes of action against Dr. Physician, Hospital A, Biobank B, Research Institute C, and Dr. Investigator. Virtually all states have some laws that affect the collection, storage, transfer, and use of

human specimens, DNA data, and health information.[133] Likewise, states often have laws regarding informed consent and medical obligations.[134] These laws may be contained in states' statutes and regulations governing human subjects research, genetic privacy, health privacy, or medical records handling and may include limits on the use (research and otherwise) and disclosure of individuals' medical information or genetic data, requirements for informed consent for such uses and disclosures, regulations governing genetic testing, and restrictions on the purpose, duration, and methods of storage of specimens and data.[135] Furthermore, property, contract, and tort laws, whether statutory or common law, may also impose rights and limits arising from the use of human specimens and DNA information. [136]

In the following subsections, we discuss these different types of laws and the possible causes of action that arise under them in our hypothetical. It is important to note that the issue of IF disclosures from secondary research involves a far broader range of legal issues than just the responsibilities of secondary researchers and just the rights of human sources of biological specimens and DNA information. Indeed, this complex matter implicates or involves a host of unsettled legal issues pertaining to the responsibilities of all researchers and the rights of all research subjects generally. Furthermore, because the biobank research system involves the transfer of materials and data from the human source to the primary collection site to the biobank to the secondary researcher, we must be concerned with the legal rights and responsibilities that exist at each link in the chain and how they might be imputed to the other links.

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133. HAKIMIAN ET AL., 50-STATE SURVEY OF LAWS REGULATING THE COLLECTION, STORAGE, AND USE OF HUMAN TISSUE SPECIMENS AND ASSOCIATED DATA FOR RESEARCH, NAT'L INS. OF HEALTH, NAT'L CANCER INST., http://www.cancerdiagnosis.nci.nih.gov/humanSpecimens/survey/index.htm (last updated Mar. 5, 2010).

134. *Id.*

135. *Id.*

136. *See* Wolf et al., *supra* note 4, at 369 ("Research subjects have also claimed that researchers
have duties arising under state common law doctrines grounded in tort, property, or contract.") (footnotes omitted).

A. MEDICAL AND HEALTH INFORMATION PRIVACY LAWS

Almost all states have laws regulating the privacy and confidentiality of individuals' medical and health information, including in many cases restrictions on the allowable uses and disclosures of such information by health care providers, insurance companies, government health agencies, and others with access to medical and health records and data. Some states define medical information as including human tissue specimens since these specimens and their associated DNA data contain significant health and medical information as well as information linking the identity of their human source.[137] For example, California's Confidentiality of Medical Information Act defines "medical information" as "any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment."[138] A more direct example comes from North Dakota's Health Information Protection Act which defines "protected health information" as:

> [A]ny information, including genetic information, demographic information, and fluid or tissue samples collected from an individual, diagnostic and test results, whether oral or recorded in any form or medium which:
>
> a. Is created or received by a health care provider, health researcher, health plan, health oversight authority, public health authority, employer, health or life insurer, school or university; and
>
> b. (1) Relates to the past, present, or future physical or mental health or condition of an individual, including individual cells and their components; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
>
> (2)(a) Identifies an individual; or
>
> (b) With respect to which there is a reasonable basis to believe that the information can be used to identify an individual.[139]

Some states' health and medical information privacy laws include provisions that allow for such information to be disclosed either generally or specifically for the purposes of research without the requirement to obtain individual informed

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137. *See* Hakimian et al., *supra* note 133, at 4.
138. CAL. CIV. CODE § 56.05(g) (West 2011).
139. N.D. CENT. CODE § 21-01.3-01 (2011).

consent or authorization if the information is first deidentified,[140] if the researchers avoid identifying the patient,[141] or if the disclosure has been approved by an IRB or some other designated authority.[142] Other states require patients' authorization or informed consent prior to any disclosures of protected health and medical information, including for research purposes. For example, Vermont's Bill of Rights for Hospital Patients states that "[p]articipation by patients in clinical training programs or in the gathering of data for research purposes shall be voluntary. The patient has the right to refuse to participate in such research projects."[143] Still many other states have statutes with no permitted disclosures of medical information for research.[144] Finally, there may be common law rights relating to privacy, consent, ownership of one's biospecimens, fraud, or patient/physician relations that are applicable to a specific situation.[145]

So how do these differing state law systems potentially

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140. *See, e.g.*, FLA. STAT. ANN. § 456.057(7)(a)(4) (2012) (permitting access to medical records "[f]or statistical and scientific research, provided the information is abstracted in such a way as to protect the identity of the patient . . . .").

141. *See, e.g.*, R.I. GEN. LAWS ANN. § 5-37.3-4(b)(3) (West 2011) ("No consent for release or transfer of confidential health care information shall be required . . . [t]o qualified personnel for the purpose of conducting scientific research . . . provided, that personnel shall not identify, directly or indirectly, any individual patient in any report of that research . . . or otherwise disclose patient identities in any manner . . . .").

142. *See, e.g.*, UTAH CODE ANN. § 26-33a-109(3)–(4) (West 2011) permitting the State's Health Data Committee to approve requests for disclosures of identifiable health information when the requesting party has received IRB approval and when the request for disclosure of information is for "a specified period" or "solely for bona fide research and statistical purposes as determined in accordance with" the rules of the Utah Department of Health.) These rules require "(i) the requesting entity to demonstrate to the department that the data is required for the research and statistical purposes proposed by the requesting entity; and (ii) the requesting entity [ ] enter into a written agreement satisfactory to the department to protect the data in accordance with this chapter or other applicable law." A person granted access to identifiable health data under these provisions "may not further disclose the identifiable health data: (a) without prior approval of the department; and (b) unless the identifiable health data is disclosed or identified by control number only."

143. VT. STAT. ANN. tit. 18, § 1852(a)(10) (West 2011).

144. Examples of states with statutes not allowing any disclosure of medical information for research include Alabama, Idaho, and Illinois. *See* Hakimian, *supra* note 133.

145. *See infra* Section III.C. for a discussion of these common law rights.

impact our hypothetical? The answer, as described more fully below, is that there is any number of potential interfaces with different state laws. These will not always be consistent as state statutory and common laws can vary.

In our hypothetical, Plaintiff can potentially recover from Hospital A for violating health and medical information privacy laws if he can bring suit in a state that recognizes tissue specimens or DNA information as protected medical information and either bars disclosure of medical information without authorization or imposes relevant restrictions on when and for what purposes medical information can be disclosed.[146] It is important to note that the types of restrictions that are relevant here are very broad because Hospital A transferred Plaintiff's specimen to a biobank for archiving and storage and not to a researcher for the purposes of research. Consequently, even if the applicable state statute permits disclosures of medical information without informed consent or authorization for the purposes of research, Hospital A has acted outside the scope of such permissible disclosures because it sent the specimen to a biobank that does not itself conduct research. This argument is especially viable in states that impose time limits on disclosures of medical and health information. Additionally, even if the state in which Plaintiff brings suit does not recognize tissue specimens as medical and health information, Plaintiff could potentially argue that access to such specimens falls within the scope and intent of medical and health information privacy laws given the massive amount of personally identifiable health and medical data that can be extracted from such tissues. Finally, Hospital A may be responsible for ensuring that whatever rights Plaintiff has are assigned or transferred to the subsequent holders of the biospecimens and subsequent researchers.

Plaintiff can also potentially recover from Biobank B, depending on the law of the state in which he brings suit, on the grounds of unauthorized use of protected health and medical information for the biobank's storage and archiving of the specimen, as well as on the grounds of unauthorized

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146. For example, a recent Minnesota Supreme Court decision, *Bearder v. State*, held that biospecimens collected from newborn infants for the state's newborn bloodspot screening program could not be used for any testing or research purposes beyond the specific purposes set forth in the enabling statute unless express consent was obtained for the additional research. Bearder v. State, 806 N.W.2d 766 (Minn. 2011).

disclosure of protected health and medical information for the biobank's transfer of the specimen Research Institute C.

Similarly, Plaintiff could potentially recover from Research Institute C and Dr. Investigator for unauthorized use of protected health and medical information if he brings suit in a state that does not permit research use of such information, even when it is deidentified, without informed consent.

There is also then the final question of whether state law requirements on the transfer of medical and health information can be interpreted as also requiring that any other obligations arising under other state statutes or common law for the use or disclosure of that medical and health information (such as an obligation to disclosure IFs) be transferred with the medical and health information. A similar theory would impose liability on the various links in the chain by which the biospecimen traveled from its initial collection to the ultimate secondary researcher. Put otherwise: did Research Institute C or Dr. Investigator have any obligation to inform (or at least attempt to inform) the original human source of the IF by virtue of someone lower in chain by which the biospecimen traveled having such an obligation?

Under general state law concepts discussed in more detail in Section C, there may be some duties arising from the researcher-research subject's relationship that require informed consent and/or disclosures of IFs to inform the human source of the biospecimen. This duty can potentially be found in a number of sources. First, such a duty is postulated by the various commentators who assert that there is some, perhaps limited, duty to inform human sources of IFs, particularly if, as is the case in this hypothetical, the IFs are material and actionable. [147] If such duties exist, then each link in the chain by which the biospecimen is transferred may be obliged to also assume those duties. In other words, one may have an obligation to transfer the biospecimen in a manner that transfers any such duties to the next entity. one may not and should not be able to avoid a duty to obtain informed consent or warn of an IF by transferring the material that is the subject of those duties without ensuring that the duties also

147. *See generally* Wolf et al., *supra* note 4, at 366–73 (discussing different sources of researchers' duties ""to offer findings of likely clinical or reproductive significance to research participants.").

transfers.[148] Finally, there may be a connection between unauthorized research and a subsequent obligation to both inform the subject of the unauthorized research and the results of that research.

B. GENETIC TESTING AND GENETIC INFORMATION LAWS

In addition to health and medical information privacy laws, almost all states also have laws on the acquisition, use, disclosure, and collection and storage of genetic materials and information.[149] These laws may govern genetic materials and information themselves or may impose requirements and restrictions on the act of genetic testing. Definitions of genetic testing, materials, and information vary significantly across states and may be found in laws with different intents and purposes including regulations of genetic testing conduct; permissible use of genetic testing, materials, and information; limits on storage (including permissible duration) and transfer of genetic materials and information; confidentiality of records containing genetic information; and informed consent requirements for conducting genetic tests, disclosing or access genetic materials and information, and performing research on genetic materials and information.

Genetic testing, materials, and information subject to these various laws arise under a number of situations, including for the purposes medical diagnosis in the clinical context, for research purposes, and for government programs such as newborn bloodspot screening. Many states' laws define genetic testing, materials, and information and distinguish requirements for genetic testing and for the use, storage, and disclosure of genetic materials and information on the basis of these different contexts. Some states' laws include broad exclusions for genetic testing and information used in the research context. One particularly broad example is Massachusetts' laws governing genetic information privacy and

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148. This can be analogized to property law concepts by which obligations (such as encumbrances, mortgages or easements) linked to property are transferred with the property or to commercial law concepts requiring the transfer of liens or other encumbrances to successors.

149. *See, e.g.*, Drabiak-Syed, *supra* note 23 at 304–05 ("[S]everal states have passed statutes governing collection of specimens and individual information for research purposes. Approximately two-thirds of the states have supplemented the federal regulation and enacted provisions specifically related to an individual's genetic information.") (footnotes omitted).

informed consent for genetic testing which defines "genetic information" as "any written or recorded individually identifiable result of a genetic test," but provides that:

> [G]enetic information shall not include any information about an identifiable person that is taken:
>
> (1) as a biopsy, autopsy, or clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA, chromosomes or proteins;
>
> (2) as a blood sample solely for blood banking;
>
> (3) as a newborn screening pursuant to section 110A; [or]
>
> (4) as confidential research information for use in epidemiological and clinical research conducted for the purpose of generating scientific knowledge about genes or learning about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease . . . .[150]

Other states' laws exclude genetic tests and information in the clinical context. For example, South Dakota's laws requiring informed consent for medical research involving genetic testing and genetic information exclude genetic tests and their derivative information obtained in the clinical context by defining a "genetic test" as:

> [A] test of human DNA, RNA, chromosomes, or genes performed in order to identify the presence or absence of an inherited variation, alteration, or mutation which is associated with predisposition to disease, illness, impairment, or other disorder. Genetic test does not mean a routine physical measurement; a chemical, blood, or urine analysis; a test for drugs or HIV infection; any test commonly accepted in clinical practice; or any test performed due to the presence of signs, symptoms, or other manifestations of a disease, illness, impairment, or other disorder.[151]

Some states use definitions that include no exclusions, research or otherwise. For instance, Oregon's genetic privacy and research laws define "genetic test" as "a test for determining the presence or absence of genetic characteristics in an individual or the individual's blood relatives, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic."[152]

Still, another important definitional difference across states is whether the definition of "genetic information"

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150. MASS. GEN. LAWS ANN. ch. 111, § 70G(a)(1)–(4) (West 2011).
151. S.D. CODIFIED LAWS § 34-14-21(2) (2011).
152. OR. REV. STAT. ANN. § 192.531(14) (West 2011).

includes or is distinguished from biological materials such as tissue samples from which genetic information can be extracted. Looking again to Oregon's genetic privacy and research laws for an example, a "DNA sample" is defined as "any human biological specimen that is obtained or retained for the purpose of extracting and analyzing DNA to perform a genetic test [and] includes DNA extracted from the specimen"[153] while "genetic information" is defined as "information about an individual or the individual's blood relatives obtained from a genetic test.[154]

'This distinction is significant in a state such as Oklahoma which allows deidentified genetic information to be used for research without informed consent, but requires informed consent for research on "[a]ll stored tissues, including blood, that arise from surgery [or] other diagnostic or therapeutic steps."[155]

One of the most rigorous regulatory regimes is that of New York, which governs confidentiality of genetic information under its civil rights laws and provides that biological samples may be used for research purposes without specific informed consent if the research is IRB approved and if the individual who is the source of the sample provided:

> [P]rior written informed consent for the use of their sample for general research purposes and did not specify time limits or other factors that would restrict use of the sample for the test, and (1) the samples have been permanently stripped of identifying information; or (2) a coding system has been established to protect the identity of the individuals who provided the samples, and an institutional review board has reviewed and approved the procedures for the coding system.[156]

The requirements for this prior written informed consent to research are extensive and include:

> (1) a statement that the sample will be used for future genetic tests;
>
> (2) the time period during which the tissue will be stored, or if no time limit is specified, a statement that the tissue will be stored for as long as deemed useful for research purposes;
>
> (3) a description of the policies and procedures to protect patient confidentiality;
>
> (4) a statement of the right to withdraw consent to use of the tissue for future use at any time and the name of the organization that

153. OR. REV. STAT. ANN. § 192.531(9).
154. OR. REV. STAT. ANN. § 192.531(11).
155. OKLA. STAT. ANN. tit. 36 § 3614.4(E) (West 2011).
156. N.Y. CIV. RIGHTS LAW § 79-1(9)(a) (McKinney 2011).

> should be contacted to withdraw consent;
>
> (5) a statement allowing individuals to consent to future contact for any or all purposes, including the following: (i) research purposes; (ii) provision of general information about research findings; and (iii) information about the test on their sample that may benefit them or their family members in relation to their choices regarding preventive or clinical care; and
>
> (6) a statement explaining the benefits and risks of consenting to future contact for the purposes set forth in subparagraph five of this paragraph. In no event shall information about specific test results on stored human tissue donated for general research purposes be disclosed to an individual without obtaining informed consent for the disclosure as [set out earlier in the law].[157]

Given the diversity of the laws, we will not dwell in detail on the range of causes of action Plaintiff may have against Dr. Physician, Hospital A, Biobank, Research Institute C, and Dr. Investigator, other than to point out that, depending on the state(s) in which he bring suits, Plaintiff may have multiple claims against each potential defendant and the strength or elements of any such claim may well vary from state to state.

A more important point for us to raise here is that there have recently been several important state judicial decisions pertaining to the unauthorized research use of biological materials obtained for other purposes, and that the courts rendering these decisions have interpreted statutory definitions and protections rather favorably toward the human source/plaintiff. The most recent of these cases, *Bearder v. State of Minnesota*, was decided by the Minnesota Supreme Court in November, 2011 and involved as plaintiffs nine families and twenty-five children claiming violations of the state's Genetic Privacy Act. In *Bearder*, the Minnesota Department of Health conducted its own research and allowed outside research organizations to conduct research using leftover blood samples from its newborn screening program without first obtaining written informed consent from the individual sources of the blood samples as required under the Genetic Privacy Act.[158] The relevant portion of the Genetic Privacy Act provides that:

> Unless otherwise expressly provided by law, genetic information about an individual:
>
> (1) may be collected by a government entity . . . or any other

157. N.Y. CIV. RIGHTS LAW § 79-1(9)(e)(1)–(6).

158. *See generally* Bearder v. State, 866 N.W.2d 766, 769 (Minn. 2011).

> person only with the written informed consent of the individual;
>
> (2) may be used only for purposes to which the individual has given written informed consent;
>
> (3) may be stored only for a period of time to which the individual has given written informed consent; and
>
> (4) may be disseminated only:
>
> (i) with the individual's written informed consent; or
>
> (ii) if necessary to accomplish purposes described by clause (2). A consent to disseminate genetic information under (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent.[159]

The first issue before the court was whether blood samples qualified as "genetic information" requiring informed consent under the Genetic Privacy Act which provides the following two definitions for "genetic information":

> (a) "Genetic information" means information about an identifiable individual derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been obtained from an analysis of:
>
> (1) the individual's biological information or specimen; or
>
> (2) . . .
>
> (b) "Genetic information" also means medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual or the individual's family members.[160]

The plaintiffs argued that blood samples qualify as genetic information because they contain DNA information.[161] The defendants argued that blood samples are biological specimens and not genetic information.[162] The court held that blood samples could not be genetic information under definition (a), as that definition applies to the information resulting from genetic testing and not to the specimen that provides that source for that information.[163] However, the court ruled that definition (b) "is broader in scope because it encompasses 'medical or biological information' about an individual. . . [and] biological information includes blood samples."[164] The court further concluded:

> [E]ven if the Genetic Privacy Act did not define the blood samples

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159. *Id.* at 771 (citing MINN. STAT. § 13.386(3)).
160. *Id.* at 772 (citing MINN. STAT. § 13.386(1)).
161. *Id.*
162. *Id.*
163. *Id.*
164. *Id.* at 773.

> themselves as "genetic information," those samples unquestionably *contain* genetic information. The Act limits the collection, use, storage, or dissemination of genetic information. It would be impossible to collect, use, store, or disseminate those samples without also collecting, using, storing, or disseminating the genetic information contained in those samples.[165]

The court then addressed whether the state's mandatory newborn screening law provided the defendants with an "expressly provided" exemption from the requirements of the Genetic Privacy Act.[166] The court concluded that the newborn screening law provided the defendants with an exemption only to the extent that the blood samples were used for the purposes of newborn screening.[167] The court held that the defendants violated the Genetic Privacy Act's restrictions on use (by using the blood samples for its own research), storage (my retaining the blood samples longer than the forty-five days allowed under the newborn screening law), and dissemination (by allowing outside researchers to use the blood samples).[168]

One of the most significant aspects of the *Bearder* decision is that it did not rely on any elements or principles of the federal regulatory oversight system. Rather, it was argued and decided purely on the grounds of state law and is an example of how state law, and not federal law, can be the principal basis for determining the rights and responsibilities of human sources and researchers.

C. CAUSES OF ACTION UNDER STATE COMMON LAW

We address issues of tort, contact, and property law jointly in this section as each area provides its own considerations but fundamentally interacts with the others. Indeed, statutory and case law pertaining to rights and obligations that arise in the context of research on human biological specimens and genetic information typically involves complex commingling of all three of these areas of law. At the heart of these tort, contract, and property law issues is the matter of informed consent. It is claims of inadequate informed consent or breach of the informed consent agreement that typically provide the basis for plaintiffs' tort actions alleging the breach of duty and

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165. *Id.* at 774.
166. *Id.* at 774–76.
167. *Id.* at 776.
168. *Id.* at 774–76.

negligence of physicians and researchers, as well as breach of contract and property right actions alleging unauthorized use, disclosure, and transfer of biological materials and genetic information by researchers. Thus, it is the informed consent agreement to which courts typically look to determine the assignment of rights and duties in such disputes. It is important to note, as previously mentioned, that federal regulations governing informed consent prohibit the use of exculpatory language that results in a research subject waiving any of his legal rights or releasing a researcher or research institution from liability for negligence.[169] While less common, there can also be state law based liability under tort, contract, or property law for the failure of researchers or biobanks to satisfy the terms and conditions set forth in the informed consent document or otherwise established by state law.

As is the case with state statutory law, causes of action arising under state common law involve a range of unsettled legal issues pertaining not only to the disclosure of IFs but also to the responsibilities of researchers and the rights of all research subjects, including human sources of biological materials and DNA information, generally.

i. Tort Law

Tort liability in negligence depends on the existence of a duty of care owed by one party to another. To be successful, a negligence claim must demonstrate: (1) that the defendant owed the plaintiff a duty of care, (2) that this duty of care of was breached, (3) that the plaintiff suffered some injury as a result of that breach, and (4) that the defendant's failure to satisfy the duty of care was the proximate cause of the plaintiff's injury.[170] The standard by which a duty of care is measured depends significantly on the circumstances of the relationship between the two parties. In most instances, courts will apply a standard of reasonable care under the circumstances and test the defendant's alleged breach against the actions of a reasonable person in the same situation.[171] However, some relationships, such as the physician-patient relationship, are recognized as requiring a higher standard.

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169. 45 C.F.R. § 46.116 (2011); 21 C.F.R. § 50.20 (2011).

170. 57A AM. JUR. 2D NEGLIGENCE § 71 (2012).

171. STEVEN E. PEGALIS, 1 AM. LAW. MED. MALP., STANDARD OF CARE, GENERALLY § 3:3 (2011).

Physicians owe patients a standard care that is reasonable not for average person but for their medical profession.[172] Physicians also have a duty to inform patients of any foreseeable risks, as well as of any interests of the physician that may present a conflict or affect the patient's decisions to undergo a particular treatment.[173] This is often viewed as a fiduciary obligation that the physician owes the patient. If a patient can prove that he suffered an injury, including the decision to not undergo treatment, due to a physician's failure to disclose a foreseeable risk or conflicting interest, the physician can be held negligent under medical malpractice regardless of any benefits that resulted for the patient. As such, the adequacy of informed consent disclosures and procedures is paramount to the satisfaction of a physician's duty of care.

In 2008, Wolf et al. conducted a comprehensive analysis of the duty of care owed by researchers to research participants.[174] The authors report that where a duty of care under a physician-patient relationship already exists, a court may extend that duty of care to include research activities undertaken by the physician.[175] For instance, the court in *Moore v. Regents of the University of California* held that a patient-plaintiff is permitted to bring an action for breach of fiduciary duty and lack of informed consent related to his physician's failure to disclosure his financial interest in removing the patient's spleen and biological specimens for non-therapeutic research use to develop a cell line.[176] Thus, Plaintiff in our hypothetical case may be able to assert a negligence claim against Dr. Physician and Hospital A based on Dr. Physician's breach of informed consent for failing to disclose to Plaintiff that his leftover specimen would be sent to a biobank for storage and future downstream research. Furthermore, the Plaintiff may be able to assert that Dr. Physician and Hospital A failed to disclose the potential benefit they would receive

172. *Id.*

173. *Id.*

174. Wolf et al., *supra* note 4, at 361–62.

175. *Id*. at 369.

176. Moore v. Regents of Univ. of Cal., 793 P.2d 479, 483 (Cal. 1990) (holding that "(1) a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and (2) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.").

(whether financial, professional, or reputational) from storing or using the biospecimen or from transferring the biospecimen for storage or use by others. Plaintiff might argue that he would not have agreed to the surgery had he known about how his leftover specimen would be used, would have consented to the use of his biospecimens only if certain returns of IFs were agreed upon, or would have refused to consent to any storage or use of biospecimens for any or particular uses or timeframes beyond those needed for immediate treatment. Plaintiff may also use the breach of the duty to support a property- or contract-based injury as discussed in subsequent sections of this paper.

It is important to note, as Wolf et al. point out, that the *Moore* court dealt only with the existing physician-patient relationship and did not address the duties of the defendant as a *researcher* to the plaintiff as a *research subject*, nor did it address the issue of human subjects research without informed consent.[177] As such, the holding in the *Moore* case does not fully identify the duties of care, if any, owed to our hypothetical Plaintiff by Biobank B, Research Institute C, or Dr. Investigator or what actions (or failures to act) may amount to a breach of those duties. In the absence of a physician-patient relationship, courts typically apply a standard duty of reasonable care to the researcher-research subject relationship.[178] Several recent cases, however, suggest that courts may be willing to recognize the existence of some special relationship between researchers and research subjects that is deserving of a higher duty of care, especially as pertains to informed consent, though the nature of this special relationship is not yet certain. In the case of *Greenberg v. Miami Children's Hospital*, the district court stated that "since the law regarding a duty of informed consent for research subjects is unsettled and fact-specific . . . , the Court finds that in certain circumstances a medical researcher does have a duty of informed consent," but declined to further elucidate as to when and how such a duty attaches.[179] In finding for the defendant, the district court identified as a factor the distinction that the

177. Wolf et al., *supra* note 4, at 369.

178. *Id.* (citing E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts On A Learning Curve*, 4 HOUS. J. HEALTH L. & POL'Y 1, 28–29 (2003)).

179. Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064, 1070 (S.D. Fla. 2003).

plaintiffs in *Greenberg*, who knowingly donated biological specimens to a particular researcher for research on a particular disease, were "more accurately portrayed as donors rather than objects of human experimentation, and thus the voluntary nature of their submissions warrant[ed] different treatment."[180] This suggests that the court might have attached a higher duty of informed consent to the research had the biological specimens not been obtained voluntarily from the donors explicitly for research, as is the case with our hypothetical Plaintiff, Research Institute C, and Dr. Investigator.

This case also opens the door to consider hybrid situations, such as the case of our hypothetical, in which the biospecimen was obtained as part of the ordinary provision of medical care and not as part of any disclosed research program. One can certainly argue that the initial relationship pursuant to which the biospecimen was obtained controls all subsequent storage or research use. Under such an approach, a later informed consent by the biobank or researcher might be required. As a note, the proposed changes to the Common Rule put forth in the ANPRM seem to run counter to this line of argumentation, as it provides lesser protections for the rights of the human source in situations in which the biospecimen is obtained outside of the research context and without any consent.[181]

One of the most significant cases in recent years to address the rights and duties that arise in the research context is *Grimes v. Kennedy Krieger Institute*, which involved a research program to evaluate the effectiveness of varying degrees of lead paint abatement in residential dwellings.[182] The researchers arranged for the study homes to be rented to families with children, most or all of whom were of lower economic standing, with the intention that the children would reside in the homes over a period of at least two years in order for the researchers to be able to test the children's blood periodically for lead contamination.[183] The same researchers had found in a prior study that the abatement methods in question created lead dust that remained in the house over time and was

180. *Id*. at 1071.
181. *See* ANPRM, *supra* note 20, at 44,515.
182. Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 811–12 (Md. 2001).
183. *Id*. at 822–23.

"particularly hazardous for children because hand-to-mouth activity is recognized as a major route of entry of lead into the body and because absorption of lead is inversely related to particule size."[184] According to the court, "[i]t was anticipated that the children, who were the human subjects in the program, would, or at least might, accumulate lead in their blood from the dust, thus helping the researchers to determine the extent to which the various partial abatement methods worked."[185] The informed consent agreement signed by the children's parents, however, did not explain that the research study would assess the success of the abatement methods by measuring the level of lead contamination in the children's blood.[186] Noting that neither the researchers nor the IRB that approved the research "saw [anything] wrong with the research protocols that anticipated the possible accumulation of lead in the blood of otherwise healthy children as a result of the experiment," the Maryland Court of Appeals looked to a wide range of authorities on ethical human subjects research standards, including international codes, treatises, and academic writings, to determine "the duties, if any, arising out of the use of children as subjects of research."[187] The court stated first that, regardless of how informed the consent, parents have no right to enlist their children in potentially hazardous nontherapeutic research.[188] The court further stated that:

> The research relationship proffered to the parents of the children the researchers wanted to use as measuring tools, should never have been presented in a nontherapeutic context in the first instance. Nothing about the research was designed for treatment of the subject children. They were presumed to be healthy at the commencement of the project. As to them, the research was clearly nontherapeutic in nature. The experiment was simply a "for the greater good" project. The specific children's health was put at risk, in order to develop low-cost abatement measures that would help all children, the landlords, and the general public as well.[189]

The court held that "special relationships, out of which duties arise, the breach of which can constitute negligence, can

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184. *Id*. at 812 (citing Mark R. Farfel & J. Julian Chisolm, Jr., *Health and Environmental Outcomes of Traditional and Modified Practices for Abatement of Residential Lead-Based Paint*, 80 AM. J. PUB. HEALTH 1240, 1243 (1990)).

185. *Id*. at 812–13.

186. *Id*. at 849.

187. *Id*. at 813–14.

188. *Id*. at 814–15.

189. *Id*. at 815–16.

result from the relationships between researcher and research subjects" based on the facts and circumstances of the particular scenario in question, even in the absence of federal or state statutes recognizing such a relationship.[190] The court further stated that:

> A special relationship giving rise to duties, the breach of which might constitute negligence, might also arise because, generally, the investigators are in a better position to anticipate, discover, and understand the potential risks to the health of their subjects. . . . This duty requires the protection of the research subjects from unreasonable harm and requires the researcher to completely and promptly inform the subjects of potential hazards existing from time to time because of the profound trust that participants place in investigators, institutions, and the research enterprise as a whole to protect them from harm. "Faced with seemingly knowledgeable and prestigious investigators engaged in a noble pursuit, participants may simply assume that research is socially important or of benefit to them individually; they may not be aware that participation could be harmful to their interests."[191]

Quite significantly, the court also stated that:

> Researchers cannot ever be permitted to completely immunize themselves by reliance on consents, especially when the information furnished to the subject, or the party consenting, is incomplete in a material respect. A researcher's duty is not created by, or extinguished by, the consent of a research subject or by IRB approval. . . . Such legal duties, and legal protections, might additionally be warranted because of the likely conflict of interest between the goal of the research experimenter and the health of the human subject, especially, but not exclusively, when such research is commercialized. There is always a potential substantial conflict of interest on the part of researchers as between them and the human subjects used in their research. If participants the study withdraw from the research study prior to its completion, then the results of the study could be rendered meaningless. There is thus an inherent reason for not conveying information to subjects as it arises, that might cause the subjects to leave the research project. That conflict dictates a stronger reason for full and continuous disclosure.[192]

The *Grimes* case is significant for the issue of IF disclosures from secondary research for several reasons. First, it demonstrates the ability and willingness of state courts to attach duties to researchers, including and beyond the duty of informed consent, which are far more stringent than those

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190. *Id*. at 846.

191. *Id*. at 851 (citing NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS 2–3 (2001)).

192. *Id*. at 850–51.

required under federal human subjects protection laws including the Common Rule.[193] It also sets forth the conflict between the interest of the researcher in the research (and his career) and the interests of the human source.[194] Critically, it shows that issues of consent and inappropriate research are, unfortunately, alive and well today.[195] The court was clearly distressed by what it perceived as a lack of concern by the researchers and IRB for the interests of the research subjects.[196] Furthermore, it shows that state courts may derive and define the duties owed by the researcher to the human subject not just from the relationship created by, and terms of, the informed consent agreement, but from the privileged ability of researchers to "anticipate, discover, and understand" their subjects' potential health risks.[197]

This ability to anticipate is closely related to another duty, the duty to warn, recognized in an earlier case, *Blaz v. Michael Reese Hospital Foundation*.[198] The plaintiff in the *Blaz* case had received x-ray therapy as a child and was notified fifteen years later by the hospital that treated him that he was at a higher risk of developing thyroid tumors as a result of the x-ray therapy, and that the hospital would provide him with follow-up evaluation and treatment at his own expense.[199] The plaintiff refused the hospital's offer for follow-up care.[200] Meanwhile, the hospital established a "Thyroid Follow-Up Project," under the direction of Dr. Schneider, to study the effects of the x-ray therapy in question.[201] Dr. Schneider submitted to the NIH a research protocol based on the Project's finding of "strong evidence" connecting the x-ray therapy to the development of several types of tumors including neural tumors.[202] Subsequently, the plaintiff was sent a questionnaire accompanied by a letter stating that the questionnaire's purpose was to "investigate the long term health implications"

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193. *See id*. at 846.
194. *Id*. at 851.
195. *See id*. at 811.
196. *See id*. at 852–55.
197. *Id*. at 851.
198. Blaz v. Michael Reese Hosp. Found., 74 F. Supp. 2d 803, 805 (N.D. Ill. 1999).
199. *Id*. at 804.
200. *Id*.
201. *Id*.
202. *Id*.

and "associated risks" of the childhood x-ray therapy the plaintiff had received.[203] The letter did not disclose, however, the "strong evidence" linking the x-ray therapy to tumor development.[204] After being diagnosed with neural tumors, the plaintiff sued both the hospital and Dr. Schneider, alleging that "they failed to notify and warn him of their findings that he might be at greater risk of neural tumors in a way that might have permitted their earlier detection and removal or other treatment."[205] Dr. Schneider argued that he had no duty to warn because he had never treated the plaintiff as a physician treats a patient.[206] In reaching a decision for the plaintiff, the court used the general criteria established by the Illinois Supreme Court for determining the existence of a legal duty: "(1) whether the harm reasonably was foreseeable, . . . (2) the likelihood of injury, (3) the magnitude of the burden of guarding against it, and (4) the consequences of placing that burden upon the defendant."[207]

The court further stated that "[a] duty to warn exists when there is 'unequal knowledge and the defendant, possessed of such knowledge, knows or should know that harm might occur if no warning is given.'"[208] The court held that "[a] reasonable physician, indeed any reasonable person, could foresee that if someone were warned of 'strong evidence' of a connection between treatments to which he had been subjected and tumors, he would probably seek diagnosis or treatment and perhaps avoid these tumors, and if he were not warned he probably would not seek diagnosis or treatment, increasing the likelihood that he would suffer from such tumors."[209] The court further stated that, even if the risk of injury were small, "placing the burden on the defendant rather than the plaintiff is the only decision that makes sense, since Dr. Schneider was in a special position to acquire the information and had in fact done so, while Mr. Blaz was in no position to find out."[210] The

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203. *Id*.
204. *Id*.
205. *Id*.
206. *Id*. at 806.
207. *Id*. at 805. (internal quotation omitted).
208. *Id.* (citing Kokoyachuk v. Aeroquip Corp., 526 N.E.2d 607, 610 (Ill. App. Ct. 1988)).
209. *Id*.
210. *Id*. at 805–06.

recognition of duties arising from the ability of researchers to foresee or identify information of health significance to research participants is a factor that is especially significant in the context of secondary research on archived specimens and DNA information because the very purpose of such secondary research is often to establish the link between particular conditions and the traits thought to be associated with those conditions. Thus, a researcher that obtains specimens from a biobank to conduct a partial or whole genome study can anticipate the possibility of an incidental discovery of health significance to the human source, including the incidental discovery of a condition for which there is no routine clinical screening.[211]

A second reason for the significance of the *Grimes* decision is that it shows that state courts may regard the intentions of researchers with suspicion if they surmise that the withholding of information or consent is a ruse to avoid obligations on the researchers or to ensure that participants enroll or do not withdraw from a study.[212] As a related matter, *Grimes* shows that state courts may prioritize the welfare and interests of individuals above the scientific and societal benefits of research.[213] Again, this is especially salient in the context of secondary research on stored specimens and DNA information because the very position of many in the research community, including the opinions informing the recent ANPRM, has been that the immense benefits of genetic research outweigh the "minimal risks" to human sources of genetic material and information.[214]

Furthermore, as some have suggested, part of the rationale for not requiring informed consent and for not returning research results and IFs to human sources of genetic material and information is the concern that not enough people will opt to participate in genetic research.[215] This sentiment underpins the decision of the court in *Greenberg* to not extend the duty of informed consent to include disclosure of the researchers' economic interest under the rationale that such a duty "would chill medical research as it would mandate that researchers

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211. *See* Wolf et al., *supra* note 45, at 223.

212. *See* Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 811–12 (Md. 2001).

213. *See id*. at 815–16, 837.

214. *See* ANPRM, *supra* note 20, at 44,516–17.

215. *See* Hansson, *supra* note 128.

constantly evaluate whether a disclosable event has occurred [and] would give rise to a type of dead-hand control that research subjects could hold because they would be able to dictate how medical research progresses."[216] The *Blaz* court also addressed this concern, but reached a different conclusion than the *Greenberg* court, stating:

> The only policy concern I can see here is that it might be thought to inhibit research into the effects of medical treatment if nontreating physicians in charge of such research programs are held to have a duty to warn the former patients of risks discovered in that research. But this does not strike me as a real worry. First, the duty would be discharged by a mere warning which, as explained, would here have been neither costly nor burdensome to give. The more costly and burdensome the warning would be to give, of course, the less likely there would be a finding of duty. Second, the medical researchers' legitimate desire for professional prestige and honor due to new discoveries would counteract any such inhibition; as of course would the concern for the well-being of its former patients which any self-respecting hospital would have.[217]

Against this rather nebulous and unsubstantial worry I must balance the fact that a finding of no duty would allow physicians in charge of hospital research programs into the risks of treatment policies to exploit the results of that research for their professional advancement and curiosity without warning the patients of any risks connected with those treatments which their research discovered, however little the cost of warning. I can see no social benefit in creating such a perverse incentive structure, particularly in view of the costs to the patients and society of preventable tumors and other illnesses. Preventative care is not an overriding good, but it is a considerable one.[218]

Thus, our hypothetical Plaintiff may have claims against the defendant physician, hospital, researchers, and institution for failing to obtain proper consent, for failing to disclose possible physician and researcher conflicts, and for failing to disclose important medical information to Plaintiff. As articulated in the previous section, Plaintiff may also have a claim against each defendant for failing to ensure the transfer of his own duties to those subsequently taking custody of

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216. Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064, 1070–71 (S.D. Fla. 2003).

217. Blaz v. Michael Reese Hosp. Found., 74 F. Supp. 2d 803, 807 (N.D. Ill. 1999) (internal footnotes omitted).

218. *Id.*

Plaintiff's biospecimen, as well as for failing to satisfy the duties of the person who had custody of the biospecimen before him.

ii. Property Law

The existence and limits of property rights to human biological specimens and genetic information is an unsettled but central matter to legal issues pertaining to the collection, use, and disclosure/transfer of these specimens and information. Under principles of property law, courts can award both injunctive and compensatory relief, as well as punitive damages to plaintiffs whose interests have been violated. There are currently no states that explicitly recognize an individual's ownership rights to his biological specimens, but at least two states, Georgia and Colorado, do have statutes that recognize individual ownership of genetic information.[219] The extent to which this ownership of genetic information is tantamount to a personal property right, however, is dubious since both Georgia and Colorado also permit such genetic information to be used for research without informed consent when the information is not individually identifiable.[220] Furthermore, the extent to which statutory silence on ownership of biological specimens and genetic information indicates whether such rights exist or do not exist is yet to be determined definitively.

Many commentators have been quick to write off issues of property law as they pertain to research on human biological specimens and genetic information in light of three seminal judicial decisions—*Moore v. Regents of the University of California*, *Greenberg v. Miami Children's Hospital*, and *Washington University v. Catalona*—all of which are often cited

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219. COLO. REV. STAT. ANN. § 10-3-1104.7(1)(a) (West 2011) ("Genetic information is the unique property of the individual to whom the information pertains."); GA. CODE ANN. § 33-54-1(1) (West 2011) ("Genetic information is the unique property of the individual tested").

220. COLO. REV. STAT. § 10-3-1104.7(5) ("Notwithstanding [provisions requiring informed consent], any research facility may use the information derived from genetic testing for scientific research purposes so long as the identity of any individual to whom the information pertains is not disclosed to any third party . . . ."); GA. CODE ANN. § 33-54-6 ("Notwithstanding [provisions requiring informed consent], any research facility may conduct genetic testing and may use the information derived from genetic testing for scientific research purposes so long as the identity of any individual tested is not disclosed to any third party . . . .").

as holding that individuals do not have property rights to their biological materials and genetic information once those materials have been legally obtained by another.[221] Strict application of the reasoning used in these cases does not support the conclusion that individuals have *no* property rights to their biological materials and genetic information.[222] Rather, these cases hold that either the *type of* property interests claimed by the plaintiffs or the facts of the specific case did not support the particular property interest or causes of action that the plaintiffs asserted.[223] Furthermore, each of these cases speaks only to a subset of the property law issues arising under the biobank research system. Indeed, questions of property rights in the context of the biobank research system and its permissible activities under federal law are broad and include:

- What ownership rights, if any, do human sources have to exclude another from possession or use of their biological materials and genetic information in the first place?
- What property rights, if any, do human sources have to set conditions and limits on the possession or use of their biological materials and genetic information by another?
- What property rights, if any, do physicians and researchers have to the biological materials or genetic information of a human source?
- What property rights, if any, does the human source retain to the biological materials or genetic information?
- What property rights, if any, do researchers have to the results of research conducted on the biological materials or genetic information of a human source? What property rights, if any, does the human source have to those research results?
- What effect does the deidentification of biological materials or genetic information have on these various property rights, if they exist?

In this section, we will first review the facts and holdings of *Moore*, *Greenberg*, and *Catalona*, and then discuss what bearing these decisions have on the questions posed above.

The *Moore* case involved a patient plaintiff, George Moore, who signed an informed consent to have his spleen removed

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221. *E.g.*, Lori Andrews, *Who Owns Your Body? A Patient's Perspective on Washington University v. Catalona*, 34 J.L. MED. & ETHICS 398, 400 (2006).

222. *Id*.

223. *Id*.

and various biological materials excised as part of his medical treatment for hairy cell leukemia.[224] The informed consent stated that the hospital could "dispose of any severed tissue or member by cremation."[225] Unbeknownst to Moore, the physician providing his treatment subsequently used his biological materials for research purposes and patented a lucrative cell line based on Moore's cells.[226] Moore sued the physician and his hospital claiming conversion of personal property, breach of duty to obtain informed consent, and breach of fiduciary duty for using the biological material without his consent.[227] The property right being asserted by Moore was the right to profit from a subsequent use of his biospecimens.[228] The court rejected Moore's claim of conversion and held that Moore's property interest in his cells, if he ever had any, were extinguished once the cells were legally removed from his body.[229] In rejecting the conversion claim, the court relied on (1) the fact that no other reported judicial decision supported the conclusion that such a continuing property interest in excised human materials exists, (2) that California's statutory law placed significant limits on the continuing interest of patients in their excised materials, (3) that Moore's cells were "no more unique to Moore than the number of vertebrae in the spine or the chemical formula of hemoglobin," and (4) that any property interests necessary to protect Moore's privacy and dignity are unnecessary due to the protections provided by the informed consent agreement that Moore signed.[230]

In *Greenberg*, the plaintiffs sued on behalf of their children who had donated blood and tissue specimens to a researcher, not for any therapeutic purpose, but specifically for the researcher's work on identifying the genetic causes of Canavan disease.[231] When the researcher developed and patented a prenatal genetic test for Canavan disease and began obtaining royalties whenever the test was used, the plaintiffs sued

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224. Moore v. Regents of Univ. of Cal., 793 P.2d 479, 481 (Cal. 1990).

225. Rohn K. Robbins, *Vail Daily column: Do you own your DNA?*, VAIL DAILY (Feb. 22, 2011), http://www.vaildaily.com/article/20110222/BIZ/110229956.

226. *Moore*, 793 P.2d at 481–82.

227. *Id*. at 480–85.

228. *Id*. at 487.

229. *Id*. at 493.

230. *Id*. at 488–93.

231. Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064, 1067–68 (S.D. Fla. 2003).

claiming that their consent to the use of the biological materials was based on an understanding that the materials would only be used for identifying the genetic cause of the disease, that the research would remain in the public domain to promote additional research on the diseases, and that any tests developed pursuant to the research would be broadly accessible and priced affordably.[232] Among their claims, the plaintiffs' alleged that they had a property interest in their biological specimens and genetic information and that the defendants engaged in conversion by using the specimens and genetic information "for the hospitals' 'exclusive economic benefit.'"[233] To support their claim of a property interest in the specimens and genetic information, the plaintiffs cited Florida's genetic testing statute which provides that "persons who contribute body tissue for researchers to use in genetic analysis do not relinquish ownership of the results of the analysis."[234] Again, the plaintiff was asserting a right to the financial proceeds or benefits from the use of the biospecimens.[235] In rejecting the plaintiffs' conversion claim, the *Greenberg* court characterized the transfer of the specimens and genetic information as "donations to research without any contemporaneous expectations of return [to the donor]."[236] The court further held that even if Florida's genetic testing statute "create[s] a property right in genetic material donated for medical research purposes, it is unclear whether this confers a property right for conversion, a common law cause of action."[237] The court's language supports the view that property rights in biospecimens or genetic material may exist in another scope.[238] The court reasoning in this case was that the state statute only provided penalties for unauthorized disclosure of genetic information or lack of informed consent to genetic testing and, as such, only conferred property rights to the extent necessary to serve those interests.[239] Interestingly, on these grounds, the Plaintiff in our hypothetical (or a plaintiff in a case of

232. *Id*.
233. *Id*. at 1074.
234. *Id*. at 1075 (citing FLA. STAT. § 760.40 (2011)).
235. *Id.*
236. *Id*. at 1074.
237. *Id*. at 1075.
238. *See id*.
239. *Id*.

unconsented transfer and research using biospecimens of the type arguably permitted under the ANPRM) might have a property claim under this statute in *Greenberg*.

The *Catalona* case involved Dr. Catalona, a physician and researcher, who, in the course of his employment at Washington University, collected biological samples removed during surgery for subsequent research on the genetic causes of prostate cancer.[240] These samples along with others collected by his colleagues were stored in the University's biorepository for prostate cancer research.[241] The individual sources of the biological samples were invited to participate in the genetic research studies and were required to sign informed consent forms indicating that the collection of samples was for medical research and not for clinical care, that the biological samples "may be used for research with our collaborators at [Washington University], other institutions, or companies," and that the participant "agree[s] to waive any claim [he] might have to the body tissues that [he] donate[s]" and also "waive[s] the right to any new material or process developed through research involving [his] tissues."[242] The consent forms also stated that "participation is voluntary and [the participant] may choose not to participate in this research study or withdraw [his] consent at any time."[243] Some, but not all, consent forms stated that participants deciding to withdraw from the research could request that their biological samples be destroyed, but noted that research results obtained prior to the request could not be destroyed.[244] Participants were also provided with an informational brochure indicating that their biological samples "may be shared with other authorized researchers doing research in similar fields at [Washington University] and other research centers," and "may be used for studies currently in progress or studies conducted 10 or 20 years from now."[245] The brochure further provided that: "You will receive no monetary payment for your tissue nor can you claim ownership rights to any medical or scientific product that results from research with your tissue."[246] Over time, both Dr.

240. Wash. Univ. v. Catalona, 490 F.3d 667, 670 (8th Cir. 2007).
241. *Id*. at 670–72.
242. *Id*. at 671.
243. *Id*.
244. *Id*.
245. *Id*.
246. *Id*.

Catalona and other University researchers transferred biological materials from the biorepository to other research institutes through the use of material transfer agreements.[247] In 2003, Dr. Catalona accepted a position at Northwestern University and sent a letter requesting that they sign a "Medical Consent & Authorization" form stating:

> I have donated a tissue and/or blood sample for Dr. William J. Catalona's research studies. Please release all of my samples to Dr. Catalona at Northwestern University upon his request. I have entrusted these samples to Dr. Catalona to be used only at his direction and with his express consent for research projects.[248]

Following this, Washington University "filed a declaratory judgment action against Dr. Catalona, seeking to establish its ownership . . . of the biological [samples]."[249] Dr. Catalona counterclaimed "that the [research participants] have the right to direct transfer of their biological samples to him" and sought an order prohibiting Washington University from using, transferring, or destroying the biological samples.[250] Shortly thereafter, eight of the research participants were joined as defendants claiming the right to direct transfer to Dr. Catalona.[251] The district court found and the court of appeals affirmed that Washington University was the sole owner of the biological samples to the exclusion of any property rights asserted by Dr. Catalona or the research participants.[252] Thus *Catalona* decided who, among two claimants, had key property rights.[253] In reaching this decision, the court, out of necessity, had to find that there were at least some property rights in the biospecimens.[254]

While often cited as establishing that human sources have no property rights in their biological materials and genetic information, these three cases, both jointly and individually, only address a subset of the property issues raised by the biobank research system and, furthermore, suggest and in some cases explicitly find that human sources do have some

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247. *Id*. at 672.
248. *Id*.
249. *Id*.
250. *Id*.
251. *Id.* at 673.
252. *Id*. at 676–77.
253. *See id*.
254. *See id*.

property rights, though not the same rights as they asserted in their claims, to their samples and information.

The issue decided in *Greenberg* and in *Moore* was whether the plaintiffs have a proprietary right to control or share in the *fruits* of research for which they voluntarily gave their biological specimens or, put otherwise, whether they have a property interest in the products that results from research using their specimens. This issue is not the same as the questions of whether (1) human sources have original property rights in their biological materials or DNA data such that they can exclude others from use in the first place and, if so, whether (2) human sources retain any residual property interests in these materials and data *themselves* after the first instances of granting use to another. The first question may seem to be addressed in *Moore*, as part of the plaintiff's claim was that no consent was obtained for the use of his cells in research in the first place.[255] However, the important and often overlooked factor in the court's rejection of Moore's claim was that Moore's assertion of property rights was to support his claim for conversion of property, a strict liability general intent tort that arises from wrongful interference with one's ownership and possessory rights.[256] In essence, the court held that Moore had relinquished any property rights he had in his cells because he did not intend to ever possess them again and because they would have no value to him even if he could regain their possession.[257] This does mean, however, that a court would not recognize a different type of property right supporting a different tort claim or a claim arising under contracts.

A simplistic analogy can been drawn to a situation in which one throws away a bunch of baseball cards that the garbage collector picks up and takes for himself. The original owner of the baseball cards relinquished his property interest in the cards when he knowingly placed them by the curb for trash removal and, thus, he has no claim for conversion against the garbage collector. However, if the garbage collector said to the owner (or, more aptly, offered the owner a written agreement), "I see that you have some old baseball cards that you no longer want. I am a garbage collector, and I will take

255. Moore v. Regents of Univ. of Cal., 793 P.2d 479, 485 (Cal. 1990).
256. *Id*. at 494.
257. *See id*. at 492.

your baseball cards to the city incinerator and burn them" and then took and used the cards for himself, the original owner may claim that he did not relinquish his ownership interest in the cards, but transferred possession to the garbage collector in the form of a bailment. It may seem that such a claim is susceptible to an argument that the original owner suffered no injury since he clearly placed no value in the baseball cards and, thus, suffered no loss as a result of the garbage collector taking the cards for himself. This is not the case, however, in the instance of biological specimens removed in the course of clinical care. Consider, instead, that unbeknownst to the original owner, his stack of old baseball cards included Bowman's 1951 classic collection worth approximately half a million dollars. Let's assume also that, unbeknownst to the original owner, the garbage collector is also an established sports memorabilia trader who had reason to know that the owner had some potentially valuable baseball cards. If the garbage collector then offered the owner of the baseball cards the same (possibly written) agreement to take and burn the cards at the city incinerator without also disclosing his status as a sports memorabilia trader, then the original owner may claim that he only relinquished his property interest in the cards because he believed they would be incinerated and that, had he known the garbage man was a sports memorabilia trader, he would have reconsidered relinquishing his rights.

Likewise, the human source of a biospecimen may well retain certain privacy or other rights under state and federal law and may also anticipate some benefit in the form of additional research and disclosure of IFs. Furthermore, the human source may well successfully assert that he relinquished control of the biospecimens only for purposes of medical care and did not consent to later research or even have any knowledge that such research might take place. A defendant researcher may be hard-pressed to successfully argue that the plaintiff knowingly relinquished any property rights relating to later research when the plaintiff had no knowledge of any such research and did not consent to such research.

This line of analysis supports the court's decision in *Moore* to overrule the defendants' demurrers to the causes of action for breach of fiduciary duty and lack of informed consent, concluding that the physician-researcher did have a duty to

disclose his financial interest in the cells excised from Moore and that Moore should be allowed to amend his claims for any injuries resulting from these breaches.[258] Such thinking is also supported by some commentators who argue that agreement between human sources of biological materials and physicians/researchers should be regarded as a partial entrustment agreement, where the human source entrusts his or her biomaterial to a trusted health care provider or researcher for specific purposes and with specific expectations.[259]

There are a number of examples of potential property rights that might exist under different state laws. First, the cases cited above analyze state property laws. Just because one state does not recognize a particular property right does not conclusively establish that a different state might not, by common law or statute, find that the very same property right does exist. Even under these cases, there may be property rights in how the biospecimen can be used, residual rights to reassert control over the property, and confidentiality rights.

To the extent that there is some property right in the biospecimen, deidentification does not and cannot eliminate any such right, even if the right is limited to a privacy interest. One has rights to property even if one's name is not on it. A mechanic grinding the VIN number off of a car does not sever any property rights of the car owner, nor does a fotomat blurring the face in a boudoir picture sever any property rights of the film owner. And, at the end of the day, one must remember that at some point in time—at least at the time of the initial sample collection—the specimen was identified and identifiable. Subsequent deliberative actions by a researcher or biobank cannot unilaterally deprive the human source of whatever property rights he might have. Allowing such a deprivation would permit a third-party to eliminate property rights without permission and for his own benefit.

iii. Contract Law

A contract is an agreement entered into by two or more parties with the intention of creating legally enforceable

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258. *See id*. at 497.

259. *See, e.g.,* Henry S. Richardson & Mildred K. Cho, Special Article, *Secondary Researchers' Duties to Return Incidental Findings and Individual Research Results: A Partial-Entrustment Account*, 14 GENETICS MED. 467 *passim* (2012).

obligations on each party.[260] Under common law principles, a party that breaches a contract may owe the non-breaching party, also called the party at loss, some remedy for the breach either in the form of specific performance of the contract, injunctive relief, or monetary damages.[261] For a contract to exist, there must be mutual assent by the parties as to the terms of the contract (also called a "meeting of the minds"), an intent by the parties to create a legal relationship, and an element of consideration understood as some bargained-for exchange of value or forbearance of a legal right that serves as inducement for mutual performance of the contract.[262] Furthermore, for a contract to be legally enforceable, all parties must have capacity to enter the contract, the purpose and the form of the contract must be legal, and the parties must consent to the contract.[263] Thus, a contract may be void or voidable[264] if it is the product of coercion, undue influence, duress, failure to disclose material information, fraud or misrepresentation in the inducement, or a lack of capacity to contract.[265]

Furthermore, third parties who receive the benefit of a contract may have obligations to one or more of the original parties to a contract under the common law doctrine of privity or under third-party beneficiary principles established under statutory and case law.[266]

The issue of whether and to what extent informed consent agreements memorialize a contractual relationship is of paramount importance to the rights and obligations of human sources and biobank research entities, as well as to the potential remedies available to human sources claiming the absence or the breach of informed consent. If an informed consent agreement is viewed as demonstrative of a contractual

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260. RESTATEMENT (SECOND) OF CONTRACTS § 1 (1981) [hereinafter RESTATEMENT].

261. *Id*. at § 345.

262. *Id*. at § 17(1).

263. *Id*. at §12.

264. Voidness refers to whether a contract ever came into existence typically because of a party's lack of intent to form the contract. Voidability refers to whether a contract can be set aside due the assertion of an affirmative defense by which a party can avoid his obligations under the contract.

265. RESTATEMENT, at § 163, 174–77.

266. 13 WILLISTON ON CONTRACTS § 37:1 (4th ed.).

relationship between a researcher and a human source, then a breach of that contract by the researcher in the form of unconsented use, transfer, disclosure, or deidentification of the human source's biospecimen or DNA data can be regarded as an injury for which the human source is entitled to a remedy.

In many respects, informed consent documents arising in the context of research are contracts in that they are enforceable only when there is intent and mutual assent by both parties and are voidable if there is coercion, duress, misrepresentation, withholding of material facts, or the like.[267] Indeed, researchers and research subjects, as well as courts adjudicating disputes between these two parties, typically look first to the language of consent documents to determine the terms of the research subject's participant in the research and the extent and limits of the researcher's allowable activities under the agreement.[268] However, the relationship created by an informed consent agreement and the rights and obligations of parties subject to such an agreement differ from those arising under conventional contract law in two important ways.

First, while contracts often serve as the genesis for a legally enforceable relationship between two parties, informed consent documents are not necessary to establish a legal relationship between researchers and research subjects. As previously described, courts may recognize the existence of a researcher-research subject relationship with legally enforceable rights and duties as arising from a tort-based duty of care.[269] Furthermore, where informed consent documents do exist, some state court decisions have used these documents to find legally enforceable arrangements other than those

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267. *See* 45 C.F.R. § 46.116 (2011) ("[N]o investigator may involve a human being as a subject in research . . . unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative."); *see also* Grimes v. Kennedy Krieger Institute, 782 A. 2d 807, 844 (Md. Court of App. 2001) (stating that informed consent agreements can create a contract and that research subjects are "entitled to *all* material information" prior to entering the agreement) (emphasis in original).

268. *See, e.g., Grimes* 782 A. 2d at 824–25.

269. *See supra* notes 205–06, 222–25, and accompanying text.

requiring a contract.[270]

Second, informed consent affords far broader protections to human subjects than would exist under common law notions of contracts.[271] These broader protections are, in one part, due to dignitary concerns for research subjects and, in another part, due to the recognition of the significant imbalance in knowledge and bargaining power that exists between researchers and researcher subjects.[272] As such, the law does not allow a research subject to agree to unreasonable or unnecessary risks, no matter how informed the consent.[273] Informed consent documents must also include far greater disclosures than would be required under contract law, including, for example, disclosures about the purpose of the research study and disclosures of alternative procedures and treatments that may be beneficial for the research subject.[274] Furthermore, while a party who breaches a contract may be liable for damages or specific performance, informed consent agreements must include a statement that the research subject may discontinue participation in the research at any time and without any penalty or loss of benefits to which he is entitled.[275] Finally, unlike contracts, informed consent

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270. *See, e.g.*, York v. Jones, 717 F.Supp. 421, 425 (E.D. Va. 1989) (holding that an informed consent agreement created a bailor-bailee relationship that, under Virginia state law, did not require a formal contract or actual meeting of the minds).

271. Here we are considering federal laws governing informed consent as providing the baseline for protections afforded to human research subjects. The Common Rule and FDA rules governing informed consent both provide that "the informed consent requirements in [these policies] are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective." 21 C.F.R. § 50.25(d) (2012).

272. Press Release, Johns Hopkins Berman Institute of Bioethics, Berman Institute Scholar Calls for a New Legal, Ethical Framework for Research with Human Tissue Specimens (June 18, 2010), http://www.bioethicsinstitute.org/web/module/press/pressid/230/interior.asp ("'Informed consent was not conceptualized as a contract between two individuals with equal bargaining power,' says Javitt, who has closely examined some of the best-known court cases involving the rights and expectations of human tissue contributors. 'Rather, informed consent is an ethical duty that the researcher owes the human subject under conditions that historically have involved unequal power.'")

273. *Grimes* 782 A. 2d at 815.

274. 45 C.F.R. § 46.116 (2012).

275. *Id*.

agreements may not include any exculpatory language that releases the researcher from liability for negligence or that waives any of the research subject's legal rights.[276]

Some commentators have argued that informed consent agreements, especially in the context of non-therapeutic human tissue and genetic research, are also different from contracts because the human source of these tissues and genetic data receive no specific benefit from the exchange and, as such, there is no consideration to support the creation of a contract.[277] This is again an instance where different state courts may reach different outcomes. A plaintiff human subject may well be able to argue that the potential improvement to medical knowledge and clinical care resulting from the research on the biospecimen or data is a sufficient benefit to the human source or that the restrictions placed on the researcher by the informed consent agreement constitute a sufficient legal detriment to the researcher sufficient to satisfy the requisite need for consideration.

As such, informed consent documents can be regarded as contracts subject to multiple regulatory interactions or as quasi-contracts. Just because an informed consent agreement satisfies the regulatory requirements for informed consent does not mean that a state court could not or would not also use that agreement as the basis for resolving a contractual dispute as to what can or cannot be done with a human source's biospecimen or genetic data covered by that agreement.

A case-and-point example of this comes from the *York v. Jones* case decided in 1989 by the District Court for the Eastern District of Virginia.[278] Plaintiffs Steven and Risa York sought the release and transfer of their frozen pre-zygote from the defendant Jones Institute for Reproductive Medicine to another institution.[279] The plaintiffs had signed a Cryopreservation Agreement with the Jones Institute that contained all the necessary components for informed consent under federal and state regulations (and which had been approved by an IRB as such) and which also contained language stating that, should the plaintiffs no longer wish to use their frozen pre-zygotes for

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276. *Id*; s*ee also Grimes* at 850 (holding "Researchers cannot ever be permitted to completely immunize themselves by reliance on consents . . . .").

277. *See, e.g.*, Ram, *supra* note 7, at 163–64.

278. York v. Jones, 717 F.Supp 421 (E.D. Va. 1989).

279. *Id*. at 422.

initiating pregnancy, the plaintiffs could choose one of three options for what to do with their remaining frozen pre-zygotes: donate them to another infertile couple, donate them for research, or have them thawed but not allowed to develop (i.e., have them destroyed).[280] The defendant refused the plaintiffs' request to transfer the frozen pre-zygotes to another institution on the grounds that the Cryopreservation Agreement limited the plaintiffs' control over the frozen pre-zygotes to only the three enumerated options set forth in the agreement.[281] The defendants further argued that, because the Cryopreservation Agreement incorporated the informed consent agreement, inter-institutional transfer could not be allowed because it had not been included as one of the options assessed and approved by the IRB.[282] In denying the defendant's motion to dismiss the plaintiffs' claims for breach of contract and quasi-contract, the district court held that the terms of Cryopreservation Agreement associated with statutory requirements for informed consent "do not conflict with any other terms of the Agreement" and that "the failure of the [IRB] to consider the ramifications of the inter-institutional transfer of cryopreserved human pre-zygotes does not vitiate the contract between these parties nor does it usurp this Court's jurisdiction to settle a contractual dispute between these parties."[283] The court further held that "the Cryopreservation Agreement should be more strictly construed against the defendants, the parties who drafted the Agreement."[284]

There are several relevant fact patterns that arise here to demonstrate how state courts may handle issues of informed consent in biobank research using principles of contract law. The first fact pattern involves the collection, use, disclosure, or transfer of a biospecimen or data when there is a refusal to consent to some or any of these activities. A human source's explicit rejection of some or any of these activities (for example, through a refusal to sign a consent agreement or through the use of an opt-out clause) would most certainly require honoring, under both principles of contract law[285] and informed consent.

280. *Id.* at 424–25.
281. *Id.* at 425.
282. *Id.* at 425–26.
283. *Id.* at 426.
284. *Id.*
285. Under contract law, such an explicit rejection may be regarded as the

It is more difficult to see how deidentification would get around such an explicit rejection.

The second related fact pattern is one involving the collection, use, disclosure, or transfer of a biospecimen or data when there is no informed consent at all,[286] a practice that has been interpreted by some as permissible under the current Common Rule and which seems to be more greatly encouraged under the proposed changes in the ANPRM. One can easily see a state court holding that a party provided with no consent or insufficient consent deserves at least as many rights and at least as much protection as a party afforded the opportunity to reject consent, especially given the *York* court's analysis that an informed consent agreement should be more strictly construed against the party who drafted it.

The third fact pattern is one where valid consent for use, disclosure, or transfer is granted for some specific purpose but is silent as to other potential uses. If that consent is later withdrawn, it is easy to see how a state court might decide that a biospecimen that can no longer be used for the research purpose stated in the informed consent agreement can also not be used for a different purpose that is not mentioned in the informed consent agreement. Again, deidentification remains a dubious argument for reaching a different outcome. Furthermore, if there is evidence to suggest that researcher obtaining the consent knew that the biospecimen would be used for another purpose than that disclosed in the informed consent agreement, then a plaintiff human source may have a claim that the informed consent should be voidable as a product of misrepresentation to induce entry into the agreement.

A final fact pattern is one similar to that in the case of *Moore* where consent to collection of a biospecimen is granted in the context of clinical care. A plaintiff human source may well be able to argue that any research use granted in such a form of consent is the product of undue influence or duress, especially if signed in the course of an emergency medical intervention. A plaintiff may also raise claims of undue influence or unconscionability resulting from the considerable power imbalance that exists between a patient and a physician,

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human source's rejection of the researcher's offer to use the source's biospecimen or data in research. No contract would be found to exist in such a scenario.

286. There can be a lack of consent due to the literal absence of any consent or due to an ineffective consent such as that in *Grimes*.

especially in the course of medical care. The issue of the validity of consent from a minor (and whether that consent must be renewed upon the person reaching the age of majority) raises even more complex issues.

Under notions of contract law and informed consent law, the rights and limitations arising from informed consent should "travel with" the biospecimen or data unless a new informed consent agreement says otherwise. It is the obligation of the person who first obtains informed consent to hold the biospecimen to ensure that the terms of that informed consent travel with the biospecimen in the event of a transfer to a subsequent holder. The subsequent holder will then have an obligation to comply with the original informed consent and to ensure its passing down the line to another subsequent holder and so on. Deidentification should not be sufficient to break any limitations established by the original consent unless so agreed to in that or in another consent. A subsequent holder may have a claim against a previous holder if the subsequent holder suffers an injury due to the failure of the previous holder to obtain or to properly transfer informed consent.

We now return to our hypothetical Plaintiff and the possible state law contract-based causes of action that he can pursue. The Plaintiff could argue that his consent to allow Hospital A and Dr. Physician to excise his tissues was limited to the scope of his clinical care and that there was no informed consent or insufficient informed consent to allow Hospital A or Dr. Physician to collect or transfer his biospecimen for storage or research use. As discussed below, this can lead to a complex situation of multiple jurisdictions with multiple common law and statutory systems being applied to a common set of facts.

D. ISSUES OF JURISDICTION, VENUE, AND CHOICE OF LAW

Our hypothetical situation demonstrates the range of procedural and substantive issues that can easily arise in the context of IFs and secondary research. Let us assume that, having established various potential causes of action arising under state statutory and common law, our hypothetical Plaintiff's attorney now begins a joint analysis of personal jurisdiction and venue to determine which states' laws are relevant for each potential defendant.

Hospital A and Dr. Physician are certainly subject to personal jurisdiction in Blue since that is the state in which

they are located, the state in which they transact their business, and the state in which the activities giving rise to Plaintiff's claim occurred.[287] Because Plaintiff was a resident of Red at the time of the activities giving rise to his potential claim against Hospital A and Dr. Physician, Plaintiff may be able to establish personal jurisdiction in Red if there exists a general or specific long arm statute authorizing such exercise of jurisdiction.[288] Absent such a statutory basis, however, it is unlikely that Plaintiff can successfully argue that Red has general jurisdiction over Hospital A or Dr. Physician on the basis of continuous and systematic activity[289] or specific jurisdiction on the basis of minimum contacts[290] given several recent court decisions rejecting personal jurisdiction over hospitals on these grounds.[291] Similarly, while Plaintiff is now a resident of Purple, it is unlikely that personal jurisdiction over Hospital A or Dr. Physician exists in this state absent a long arm statute.

With respect to Biobank B, Plaintiff can establish personal jurisdiction in the state of Green where Biobank B is located

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287. Int'l Shoe Co. v. Washington, 326 U.S. 310, 316–17 (1945).

288. *See, e.g.,* CAL. CIV. PROC. CODE § 410.10 (West 2012).

289. *See* Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 415–16 (1984) (holding that, in order for a court to exercise general in personam jurisdiction over a party, the party must have "continuous and systematic" contact with the forum state unless the party's contacts with a forum state are related to the cause of action in question).

290. *Int'l Shoe*, 326 U.S., at 316 (holding that a court may exercise specific in personam jurisdiction over a party if the party has sufficient minimum contacts with the forum state such that maintain the suit there does not "offend traditional notions of fair play and substantial justice.").

291. *See, e.g.*, Zavala v. El Paso County Hospital, 172 P.3d 173 (N.M. 2007). In this case, the Court of Appeals of New Mexico affirmed a district court's finding that it lacked jurisdiction to hear a lawsuit filed by New Mexico resident plaintiffs against two Texas doctors and a Texas hospital. The Court rejected the plaintiffs' claims that general and specific personal jurisdiction existed despite a patient transfer contract between the Texas hospital and a New Mexico hospital, a large number of New Mexico residents treated at the Texas hospital, the Texas hospital's status as a registered Medicaid provider in New Mexico, and the Texas hospitals accreditation as a regional trauma center serving the border region between Texas and New Mexico. The Court instead relied on the defendants' claims that the Texas hospital did not intentionally solicit New Mexico patients. The Court concluded that subjecting the Texas Hospital to personal jurisdiction in New Mexico would offend traditional notions of fair play and substantial justice because New Mexico's interest protecting the rights of its citizens was mitigated by the fact that the injury took place out of state and outweighed by considerations for fairness, efficiency, and public policy. *See also* Harlow v. Children's Hospital, 432 F.3d 50 (1st Cir. 2005).

and transacting business and where the unauthorized use of the biospecimen took place, giving rise to Plaintiff's claims. Jurisdiction may also exist in Red or Purple depending on the existence of a long arm statute. Plaintiff may also be able to establish personal jurisdiction against Biobank B in the state of Blue on the grounds that Biobank B had sufficient minimum contacts with Blue as evidenced by its knowing and intentional practice of obtaining biospecimens from a hospital in Blue and by its purposeful availment of Blue's informed consent laws that governed the collection and transfer of the biospecimen in question.[292] If Plaintiff can adequately state a claim that the injuries he suffered as a result of the undisclosed IF were in part due to Biobank B's failure to obtain informed consent or to Biobank B's unauthorized transfer of the biospecimen to Research Institute C, then Plaintiff may also be able to argue that Biobank B should be subject to personal jurisdiction in the state of Yellow since Biobank B knowingly and intentionally transferred the biospecimen to a research institution in that state and as such could reasonably anticipate being subject to a suit in that state pertaining to that transfer.[293]

Finally, with respect to Research Institute C and Dr. Investigator, there is personal jurisdiction in the state of Yellow and potentially in Red or Purple on the basis of the same analysis used above. Research Institute C and, perhaps, Dr. Investigator may also be subject to personal jurisdiction in the state of Green where Biobank B is located because they intentionally obtained their biospecimens from there and availed themselves of Green state law governing informed consent and the transfer of biomaterials.

It is likely that a suit by Plaintiff against one or several of these potential defendants would result in a complex web of cross claims, joinders, impleaders, and the like. As such, we

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292. *See* United States v. Swiss American Bank, Ltd., 274 F.3d 610, 623-24 (1st Cir. 2001) ("The purposeful availment inquiry . . . focuses on the defendant's intentionality. This prong is only satisfied when the defendant purposefully and voluntarily directs his activities toward the forum so that he should expect, by virtue of the benefit he receives, to be subject to the court's jurisdiction based on [his contacts with the forum].").

293. *See* World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980) (explaining that a court's ability to exercise personal jurisdiction can depend on whether "the defendant's conduct and connection with the forum State are such that he should reasonably anticipate being haled into court there.").

will not belabor the intricacies of which state's law a court might decide to apply. Our point, simply stated, is that each collection site, biobank, and secondary researcher in the biobank research system faces a veritable patchwork of state laws under which it might be accountable. The decision to avoid informed consent and return of IFs through deidentification practices permissible under federal law may be expeditious and may reduce administrative and financial burdens in the short term—but in the longer term, such a decision may very well prove to be far more costly and burdensome than expected.

E. STATE LAW IS NOT PREEMPTED BY FEDERAL REQUIREMENTS

As we demonstrate, both federal and state law applies to research using biospecimens, the rights and obligations of biobanks and researchers, and the rights of human sources. An obvious question is whether the federal system preempts state laws (whether common law or statutes) that might provide additional or different rights and obligations. Indeed, researchers or research institutions that do not wish to be subject to these various state law systems might well try to argue that the federal system—notably the Common Rule and FDA analog—should preempt state law requirements.

Overall, preemption is based on the Supremacy Clause in the United States Constitution.[294] Under the Supremacy Clause, the federal government can (absent some specific restriction such as the 21st Amendment[295]) establish laws or regulations within its sphere that override state law. In the case of research on human biospecimens and genetic data, there can be federal control based on either the use of federal funds to directly or indirectly support the research in question[296] or upon interstate commerce.[297]

Given the breadth of federal funding of research and the breadth of the interstate commerce clause, it is hard to imagine any significant research which could be totally outside of federal oversight. However, just because the federal government has the Constitutional authority to exercise oversight or even has exercised oversight does not mean that

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294. U.S. CONST. Art. VI Clause 2.

295. U.S. CONST. amend. XXI.

296. Note that the current Common Rule is largely based on federal research funding.

297. U.S. CONST. art. I, § 8, cl. 3.

states cannot also exercise oversight. The question of whether these state oversight schemes can exist along with the federal system is answer by the law surrounding preemption.

There are three general types of preemption which could provide the result desired by these stakeholders: express preemption, implied or field preemption, and conflict preemption. Express preemption exists when Congress has explicitly stated its intent that the oversight or regulatory system it has created replaces all state or local systems.[298] This requires an express statement of congressional intent to preempt. A classic express preemption case is *Riegel v. Medtronic*.[299] Riegel involves a state product liability case over an allegedly defective medical device. In 1976, Congress enacted 21 U.S.C. § 360k which states, in relevant part:

> (a) General Rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.[300]

The Supreme Court analyzed this express preemption provision and rules that any state law claim that was "different from, or in addition to" a federal provision was preempted meaning that the state action must be dismissed.[301]

However, there is no federal statutory equivalent to § 360k (or other similar congressional pronouncements) in the Common Rule or FDA analog. In fact, as previously discussed, both the Common Rule and the FDA analog contain provisions expressly stating that human subjects retain any rights they have under other federal, state, or local laws and that researchers cannot waive liability under these other laws. As such, researchers' arguments for express preemption would fail.

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298. English v. General Elec. Co., 496 U.S. 72, 78–79 (1990).

299. Riegel v. Medtronic, Inc., 552 U.S. 312, 315 (2008).

300. 21 U.S.C. § 360k (2006).

301. *Id*. at 327–28. The Court left open the possibility of a state action that is "parallel" to the federal system. For example, if FDA required a specific label on a medical device and the defendant failed to include the required language on the label, the plaintiff's claim (assuming proximate causation) might well be a "parallel" claim under Riegel and permitted to continue.

The second type of preemption is implied or field preemption. Courts look to see whether the federal government has so occupied a field as to imply intent to preempt state law.[302] Courts also look to see whether the Congressional purpose behind the federal law would be frustrated by other state oversight systems or requirements.[303] Given the historical role of the states in protecting their citizens and in regulating the practice of medicine, health care provider interactions with patients, and requirements for informed consent, implied preemption would be difficult, if not impossible to establish. As we discuss above, state legislatures have been active in establishing state statutory systems applicable to much of the research at issue. This further demonstrates the well-accepted role of the states in protecting its citizens and in regulating research within their borders.

The Supreme Court recently refused in *Wyeth v. Levine* to find implied preemption in a product liability case involving a prescription drug and arising under Vermont state law. [304] Note that both the medical device in *Riegel* and the drug in *Levine* are regulated federally by the FDA. However, because (1) the express preemption provisions of § 360k apply only to medical devices and (2) there is a historic role for states in tort law, the Supreme Court refused to find implied or field preemption in the case of *Levine.*[305] And yet, the federal oversight of drugs and medical devices is orders of magnitude greater than is federal oversight of research. If this more extensive regulatory system was not sufficient to establish preemption, then the less regulated world of research will also not be preempted.[306]

Finally, there is conflict preemption (also known as impossibility preemption). If the federal and state requirements cannot both be satisfied, the federal requirement prevails.[307] Conflict preemption is a difficult case to establish and requires either a literal impossibility to satisfy both federal

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302. Gade v. National Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992).

303. Wyeth v. Levine 555 U.S. 555, 575 (2009).

304. *Id.*, at 580–81.

305. *Id.*, at 565.

306. Interestingly, key physician groups such as the *New England Journal of Medicine* opposed preemption in both cases. It would seem that they would be hard pressed to argue for preemption only in a situation in which it was to their benefit.

307. Gibbons v. Ogden, 22 U.S. 1 (1824).

and state requirements (actual conflict)[308] or a demonstration that the state law is "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[309] Requirements which are additive or more restrictive generally do not trigger conflict preemption. The Common Rule and FDA analog rarely create a requirement that could conflicts so directly with a state requirement.

When considering conflict preemption, it is critical to understand that a state can impose substantially greater requirements or additional requirements without triggering conflict preemption. Just because the Common Rule does not require a particular disclosure or permits a particular type of research does not preempt a state requirement for more disclosure or for limiting certain research.

As such, absent Congress intervening and enacting an express preemption statute, researcher will be unable to succeed with a preemption defense. It is interesting to note that the defendants in cases such as *Bearder*, *Grimes*, and *Greenberg* did not raise any meaningful preemption defenses. Preemption offers the biobank research system little comfort if they face state law based tort, contract, property, or other claims.

CONCLUSION

While there is growing attention to the issue of incidental finding disclosures from secondary research using biospecimens and genetic data stored in biobanks, the focus of this attention has been too narrow in several ways. First, there has been little attention brought to the growing discordance between the practices allowed under federal human subjects research regulations and the very principles by which these regulations are to protect the rights and welfare of human research subjects—namely incentives created by the Common Rule for researchers to deidentify biospecimens and data in order to avoid requirements for informed consent, IRB review, and disclosures of IFs. Second, there has been little attention paid to the pivotal role that state laws play in determining the rights of human subjects and the responsibilities of

308. Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–143 (1963).

309. Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

researchers.

In many ways, the apparent decision of some in the research community to hang their hats on the federal law is one of familiarity and convenience. Researchers are accustomed to dealing with the Common Rule. State courts and legislatures are more complex and fragmented. State institutions, by nature of being presented with different and unfamiliar issues arising from a nascent technologies and new forms of research, have proceeded cautiously (though not unreasonably so given the breadth of the issues) to fully digest and decide how state statutes and common law principles interact with the complex problems put before them. In several instances state courts or legislatures have decided cases in great favor of researchers and the enterprise of biomedical research. However, a great majority of the relevant court cases demonstrate that it is state law and not federal law that is deciding and will continue to decide the rights and responsibilities that arising from the collection, use, and transfer of biospecimens and genetic data. A growing number of states are enacting their own statutory regimes to provide human sources of these biospecimens and data with protections often greater than those provided under federal laws. So, too, are we seeing a growing number of state judicial decisions, such as the Minnesota Supreme Court decision in *Bearder*, in which courts are construing applicable laws favorably for plaintiff human sources or, as in *Grimes*, outright calling into question the underlying motivations of researchers and IRBs in forgoing disclosures and informed consent.

Indeed biobank research entities are being faced with two emerging tides—a federal tide washing away some of the protections afforded research subjects and a state tide bringing to shore new, often stronger, protections. The rush of researchers to surf the first wave may very well end with getting slammed by the second wave.