

TIERED CONSENT AND THE TYRANNY OF CHOICE

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ABSTRACT

Regulations and doctrine governing human tissue research are facing immense pressure to ensure respect for the interests of tissue providers and of researchers. Tiered consent presents tissue providers with a menu of research categories to which they may consent, and it is a recognized best practice. Yet, evidence in consumer psychology suggests that abundant choice causes decision-makers to experience information overload, make arbitrary choices, refrain from choosing altogether, and experience regret following decision-making. These patterns result in systematically lower quality decision-making. This Essay fleshes out the potential limitations of expanded choice in tiered consent situations so that use of this best practice, and the laws and doctrine governing it, best approaches the ethical paradigm of informed consent.

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Ne quid nimis. (In all things moderation.)

—Publius Terentius Afer (Terence)

I. INTRODUCTION

In modern medicine, informed consent is a touchstone of ethical and legal practice. Doctors must obtain freely given and informed consent from patients before engaging in touching or treatment of any kind (except in certain circumstances, such as emergencies or where full information would, in fact, be detrimental to patient health), and researchers are held to an even stricter standard to divulge all material risks in obtaining participant consent. Yet, informed consent requires much more than simply the provision of information, and obtaining adequate consent can be difficult as science moves forward and human tissue is its medium for experimentation. With the advent of genetic analysis, researchers hope to identify disease-related and other genes and to measure the frequency of such genes' occurrence across large populations. This kind of research requires massive cross-sectional bio-repositories of samples available for study. Already, more than 300 million tissue samples from more than 178 million individuals are stored in the United States, and this number grows by more than 20 million samples every year.¹

Careful consideration of the process of consent in the context of medical research using human tissues is needed. Although consent for research purposes is not a new concept, consent for the research use of human tissues poses new ethical problems. Unlike other kinds of research

¹ ELISA EISEMAN & JASEN J. CASTILLO, HANDBOOK OF HUMAN TISSUE SOURCES: A NATIONAL RESOURCE OF HUMAN TISSUE SAMPLES, at xvii (1999). In 1998, the National Bioethics Advisory Commission (NBAC) similarly reported that more than 282 million tissue samples were stored in the United States, accumulating at a rate of more than 20 million new samples per year. NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 13 (1999), *available at* <http://www.georgetown.edu/research/nrcbl/nbac/hbm.pdf>.

involving human subjects, research using human tissues can extend over long periods of time and a single sample may be used in multiple (potentially unrelated) studies. In this sense, human tissue research is unique among research involving human subjects because of the scope of potential choice available to tissue providers—in theory, tissue providers might wish to consent to one, many, or all kinds of research, present and into the future.

Federal regulations and judicial doctrine govern large swaths of research involving human subjects, but, as yet, agencies and courts have been unwilling to apply the necessary protections of informed consent to human tissue research.² Our national commitments to creating regulations for the ethical conduct of research,³ however, and our interests in facilitating effective and efficient research both point to the need for reform. Policymakers, ethicists, and researchers must find ways to adapt traditional doctrines and policies of informed consent to situations in which as few as one consent-generating interaction may give rise to multiple uses of a person's tissue, genetic information, or other personal data.

Tiered consent—which provides potential tissue providers with a menu of research categories to which they may consent—has been proposed as a “best practice” for moving forward ethically with human tissue research.⁴ The availability of options enables providers to exercise some level of control over the future use of their tissues, while limiting the administrative and other burdens that diminish the effectiveness of consent models requiring frequent re-contact. However, recent data emerging about consumer psychology raise flags about

² See *infra* Section II.B.

³ See NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979).

⁴ See, e.g., ELISA EISEMAN ET AL., CASE STUDIES OF EXISTING HUMAN TISSUE REPOSITORIES: “BEST PRACTICES” FOR A BIOSPECIMEN RESOURCE FOR THE GENOMIC AND PROTEOMIC ERA 137 (2003), available at <http://www.rand.org/pubs/monographs/MG120/> (follow “Full Document” hyperlink); NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 1, at 64-65; see also Natalie Ram, *Regulating Consent to Human Embryo Research: A Critique of Health Canada's Proposal*, 14 HEALTH L. REV. 19 (2005).

the shortcomings of radically expanded choice. These data indicate that while some choice appears to be beneficial—and therefore tiered consent is likely to remain a best practice—too much choice actually causes anxiety in decision-makers as well as attempts to opt-out of decision-making altogether or to choose at random.⁵ There is good reason to believe that these behavior patterns will manifest as strongly, if not more so, in the context of tiered consent.⁶ Therefore expanding the choices available to tissue providers too much will undermine, rather than buttress, the principles underlying informed consent. These findings are of no small import; national regulation and judicial doctrine play a central role in establishing boundaries for ethical research in the United States. Thus, policymakers, as well as bioethics and legal scholars, need to account for the effects of abundant choice in identifying, advocating for, and implementing appropriate consent guidelines for human tissue research.

This Essay aims to flesh out the potential limitations of expanded choice in tiered consent situations so that use of this best practice, and the laws and doctrine governing it, best approaches the ethical paradigm of informed consent. Although the ethical components of informed consent for the use of human tissue in research, as well as their implementation in law, have been the subject of much discussion, authors have neglected the insights into decision-making offered by studies in behavioral economics and decision-making psychology.⁷ Likewise, most scholars of behavioral economics and decision-making psychology have not paid

⁵ See *infra* Part III.

⁶ See *infra* Part IV.

⁷ See, e.g., Ellen Wright Clayton et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 JAMA 1786 (1995) (presenting the consensus statement emerging from a workshop of scientists, ethicists, lawyers, and consumers convened by the National Institutes of Health and the Centers for Disease Control and advocating a tiered consent and re-contact model for the use of human tissue in research); Philip R. Reilly, Mark F. Boshart & Steven H. Holtzman, *Ethical Issues in Genetic Research: Disclosure and Informed Consent*, 15 NATURE GENETICS 16 (1997) (arguing for broader disclosure in informed consent to the use of tissue for gene mapping research); David Wendler, *One-Time General Consent for Research on Biological Samples: Is it Compatible With the Health Insurance Portability and Accountability Act?*, 166 ARCHIVES INTERNAL MED. 1449 (2006) (arguing that a two-step consent process is required to comply with the requirements of HIPAA). See generally 2 RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE: COMMISSIONED PAPERS (2000).

significant attention to the interactions between their findings and the principles of informed consent generally, much less tiered consent. This Essay begins to fill in these blanks. Part II provides a primer on the notion of “informed consent,” explicating why informed consent is essential to ethical and productive research using human tissues, describing the ethical and legal standards for informed consent, and identifying three primary models for obtaining consent in the context of human tissue research. Part III explores recent findings on the psychology of decision-making in the consumer context, and Part IV applies these findings to tiered consent for human tissue research. Part V concludes, identifying areas for future research and highlighting the critical role that law and policy, enriched with an understanding of decision-making psychology, must play in shaping the future of human tissue research.

II. THE THEORY AND LAW OF INFORMED CONSENT

A. *Why Consent Matters to the Research Use of Human Tissues*

The right to decide whether and how one’s body and its parts may be used in research has been described as a “fundamental” right,⁸ although courts have yet to recognize such strong protection for providers of human tissue for research. Respect for the interest of tissue providers in controlling the ways in which their tissues, and the information contained in their cells, are used flows in part from respect for human dignity. Human dignity demands that all persons be treated not merely as means to an end, but also as ends in themselves.⁹ When individuals are made tissue providers without their knowledge and authorization, they may suffer the harm of

⁸ Robert M. Sade, *Research on Stored Biological Samples is Still Research*, 162 ARCHIVES INTERNAL MED. 1439 (2002).

⁹ IMMANUEL KANT, GROUNDWORK OF THE METAPHYSICS OF MORALS 38 (Mary Gregor trans., Cambridge Univ. Press 1997) (1785); see also Sade, *supra* note 8, at 1440 (arguing that tissue providers should be referred to as “research subjects” rather than as “sources” because the latter term “suggest[s] that [tissue providers] are things rather than willing persons”).

physical invasion and deprivation of their autonomous right to be let alone.¹⁰ When individuals are not adequately equipped with information pertinent to their decision about whether or not to participate in a course of action, be it medical treatment, direct participation in research, or the provision of tissue for research, they suffer a dignitary harm by being deprived of their autonomous right to choose.¹¹

Concern for tissue providers' interest in control is not merely academic. Many people invest every use of their body, or pieces of it, with moral and ethical significance. Orthodox Jews, for example, often hold religious beliefs that the body must be buried whole; indeed, "if a person's leg is amputated during his or her life, arrangements are made to store that body part for burial with the individual after death."¹² Many Native Americans hold similar beliefs about the integrity of the body.¹³ Limitations short of absolute refusal to the research use of tissues may also arise:

some people may wish to limit the use of their samples to noncommercial entities. Others may wish to forbid the use of their samples to investigate certain disorders, particularly if the disorders are stigmatizing for a specific population group, such as an alcoholism gene might be. In addition, retaining tissue samples or immortalizing cell lines may violate cultural or religious beliefs.¹⁴

Thus, informed consent—really, informed choice—plays a critical role in protecting tissue providers' interest in control. As such, informed consent is fundamentally an expression of respect for human dignity: "To say that one cannot be bound by a promise that one did not

¹⁰ See Maryjoy Ballantyne, *One Man's Trash is Another Man's Treasure: Increasing Patient Autonomy Through a Limited Self-Intellectual Property Right*, 3 GEO. J.L. & PUB. POL'Y 567, 576 (2005).

¹¹ *Id.*

¹² Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED. & ETHICS 22, 25 (2005).

¹³ NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 1, at 49.

¹⁴ Clayton et al., *supra* note 7, at 1789.

voluntarily and knowingly make is to say that the individual should be the author of her own undertakings, that a genuine respect for her dignity requires a broad deference to her choices.”¹⁵

Yet, respect for the tissue provider’s interest in control, and therefore a requirement for informed consent, emerges not only from considerations of respect for human dignity, but also from more consequentialist considerations about maximizing the amount of tissue available for research. Individuals may refuse to provide tissue for research if they fear that their interest in controlling the future uses of their cells and genetic information will not be respected. More troubling still is the possibility that concerns about the future use of cells obtained during routine medical care may cause individuals to forego such care. This is been reported anecdotally among African American women, who, recalling past abuses in medical interventions and research involving African Americans such as “the infamous Tuskegee syphilis experiment and the chaotic conditions attending early sickle-cell anemia carrier trait screening,”¹⁶ have refused prenatal diagnosis out of fear about other uses that might be made of their amniotic tissue.¹⁷ Thus, respect for informed consent has both a deontological and a utilitarian basis.

Moreover, a tissue provider’s interest in control over the use of her tissue in research embraces a number of important derivative interests, including confidentiality and commercialization. A tissue provider’s interest in confidentiality is both an instrumental and fundamental privacy interest in protecting the provider from the negative impact of unwanted

¹⁵ Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 900 (1994); see also Allen Buchanan, *An Ethical Framework for Biological Samples Policy*, in 2 RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE: COMMISSIONED PAPERS, supra note 7, at B-1, B-16 (“Informed consent is primarily a protect [sic] against nonconsensual bodily invasions and against dignitary harms that can generally be ranked under the category of treating persons disrespectfully, as if they were mere means for the pursuit of others’ ends.”).

¹⁶ Rayna Rapp, *Refusing Prenatal Diagnosis: The Meanings of Bioscience in a Multicultural World*, 23 SCI. TECH. & HUM. VALUES 45, 49 (1998).

¹⁷ Dorothy Nelkin & Lori B. Andrews, *Introduction: The Body, Economic Power and Social Control*, 75 CHI.-KENT. L. REV. 3, 7 (1999) (citing Rapp, supra note 16); see also Donna T. Chen et al., *Research With Stored Biological Samples: What Do Research Participants Want?*, 165 ARCHIVES INTERNAL MED. 652 (2005) (reporting an empirical study showing that, given the option to permit all future research use of their tissues, African Americans were less likely than whites to provide this unlimited authorization).

disclosure of information about the provider that is discovered through research. If third parties such as insurance providers or employers gain access to this information, individuals may be denied health or life insurance coverage, or they may lose their jobs on account of anticipated health problems.¹⁸ Unrequested disclosure of information to the tissue provider or her family may also cause distress or embarrassment.¹⁹ These concerns pertain primarily to research involving genetic analysis, as genetic information can serve as a basis for predictive diagnosis of future medical conditions or health risks.

The interests that tissue providers advance concerning the commercialization of products derived from their cells tend to follow one of two lines. One expression of interests in commercialization contends that the commercialization of body products is wholly unethical. This focal point arises because some individuals have moral, ethical, or religious objections to the commercialization of pieces of the human body²⁰ or concerns about the coercion and

¹⁸ See DOROTHY NELKIN & LAWRENCE TANCREDI, DANGEROUS DIAGNOSTICS: THE SOCIAL POWER OF BIOLOGICAL INFORMATION 4, 7 (1989); Ted T. Ashburn, Sharon K. Wilson, & Barry I. Eisenstein, *Human Tissue Research in the Genomic Era of Medicine*, 160 ARCHIVES INTERNAL MED. 3377, 3378 (2000) (noting that “there have been many documented cases of insurance and employment discrimination based on an individual’s genetic makeup”); see also Sheryl Gay Stolberg, *President Calls for Genetic Privacy Bill*, N.Y. TIMES, Jan. 17, 2007, at A14 (reporting on President Bush’s urging to Congress to pass a genetic privacy bill because “[i]f a person is willing to share his or her genetic information, it is important that that information not be exploited in improper ways” and “[w]e want medical research to go forward without an individual fearing personal discrimination”).

¹⁹ See Stewart A. Laidlaw, Leslie J. Raffel, & Judith F. Daar, *Genetic Testing and Human Subjects in Research*, 24 WHITTIER L. REV. 454, 460 (2002) (“Emotional or psychological harms from learning one is a carrier of a genetic disease can be devastating. This is particularly true when the onset of the disease is a virtual certainty, such as in the case of Huntington’s disease.”); see also Sonia M. Suter, Note, *Whose Genes Are These Anyway? Familial Conflicts over Access to Genetic Information*, 91 MICH. L. REV. 1854, 1860 (1993) (“Genetic data are also unique in how they may affect self-identity. Empirical evidence shows that the knowledge or assumption that one carries certain disease genes can affect self-perception.” (citation omitted)). If genetic analysis in research exposes mismatched paternity, this is likely to be stressful to existing family relationships as well as embarrassing to all parties involved. See Susan M. Denbo, *What Your Genes Know Affects Them: Should Patient Confidentiality Prevent Disclosure of Genetic Test Results to a Patient’s Biological Relatives?*, 43 AM. BUS. L.J. 561, 598 & n.162 (2006) (noting that “the revelation of genetic test results to family members may cause a special type of harm, one that some commentators have labeled the ‘family secrets’ problem”).

²⁰ See NAT’L BIOETHICS ADVISORY COMM’N, *supra* note 1, at 49 (“Some individuals may object to the possibility that researchers could sell their samples to companies for profit.”); Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849 (1987).

exploitation of those providing tissue.²¹ Alternatively, tissue providers may argue that those who provide the raw materials of research should share in the economic benefits of the fruits of that provision.

Thus, tissue providers advance a number of strong claims, both deontological and instrumental, for why their preferences and choices should matter in research involving human tissue. Respect for provider consent therefore plays an essential role in creating a legal framework in which ethical research can take place.

B. What Consent Requires

Accepting that consent remains vital in the context of human tissue research, the question then becomes what consent requires. In a classic treatise on consent, Ruth Faden and Tom Beauchamp identified five necessary elements of consent: disclosure; understanding; voluntariness; decision-making capacity or competence; and authorization.²² Each of these facets of consent imposes duties on practicing medical professionals and research scientists. Disclosure requires professionals to impart necessary and material information to patients and/or research subjects. Much emphasis and academic and professional literature focuses on the disclosure aspect of consent. Indeed, the emphasis on disclosure is evident even in the term of art “informed consent,” which stresses the availability of information.

²¹ See, e.g., *Oversight Hearing on the Implementation of Proposition 71, the Stem Cell Research and Cures Act: Joint Hearing Before the California Senate Subcommittee on Stem Cell Research Oversight, Senate Health Committee, and Assembly Health Committee*, 2005 Leg. (Mar. 9, 2005) (statement of Francine Coeytaux, MPH, Pro-Choice Alliance for Responsible Research), available at http://www.genetics-and-society.org/resources/items/20050309_senate_coeytaux.html (noting that so long as financial inducement is available, most human eggs obtained for human cloning research will come from poor women); Donna Dickenson, *Commodification of Human Tissue: Implications for Feminist and Development Ethics*, 2 DEVELOPING WORLD BIOETHICS 55 (2002) (arguing that human eggs required for cloning research are likely to come from women in the southern hemisphere and support research in the northern hemisphere and available only to those in the North). In many of these instances, those who bear the burden of producing tissue for research may not be the ones who enjoy the benefits flowing from research.

²² RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* (1986).

Despite less focus in the relevant literature, the other four aspects of consent are also critical. Understanding requires that professionals ensure that information is intelligible to non-medical experts and that individual patients have understood the information disclosed to them. Like disclosure, understanding is crucial to ensuring that consent is “informed.” Voluntariness demands that consent be freely given. Excessive physical, mental, or even financial inducements to consent are unethical and vitiate consent because the notion of consent is meaningless where no true option of refusal exists. Decision-making capacity informs the elements of understanding and voluntariness by requiring that patients or research participants (or their legal representatives) be competent to understand and make decisions. Competence is necessary to ensure that vulnerable persons are not exploited and that those providing consent are legally and ethically capable of doing so. Finally, although the word “authorization” lends itself to the affirmative decision to proceed, it is meant to signify that the individual in question must make an affirmative decision either to proceed with or to refuse the proposed medical or research intervention.

These five principles of consent underlie and animate legal doctrines of consent as well. Where consent is inadequate or incomplete, patients and research participants have successfully brought tort claims arising under battery and negligence. Competency is critical to legal claims regarding consent, as minors and incompetent persons are generally legally unable to provide valid consent.²³ Where medical professionals perform procedures or engage in touching without authorization from patients/participants, they may face claims of battery.²⁴ Likewise, where

²³ This is general rule and ages of consent in particular are often established by statute.

²⁴ *See, e.g.,* *Bang v. Charles T. Miller Hospital*, 88 N.W.2d 186 (Minn. 1958) (“[W]here a physician or surgeon can ascertain in advance of an operation alternative situations and no immediate emergency exists, a patient should be informed of the alternative possibilities and given a chance to decide before the doctor proceeds with the operation.”).

consent has been coerced, tort doctrine dictates that such consent is invalid and a battery has occurred.

Where medical professionals fail to adequately disclose material risks to a procedure, they may be subject to tort liability under negligence. The modern legal doctrine defining the medical duty to disclose is established in *Canterbury v. Spence*, which stated:

True consent to what happens to one's self in the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible.²⁵

Under *Canterbury*, physicians have a general legal duty to disclose all material risks—material risks being those that “a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to . . . in deciding whether or not to forego the proposed therapy.”²⁶ In this fashion, legal doctrine has attempted to incorporate ethical principles governing consent.

Similarly, federal regulations governing human subjects research have also been structured around the ethical principles of informed consent. In the United States, research involving human

²⁵ 464 F.2d 772, 780 (D.C. Cir. 1972) (citations omitted). The modern legal baseline for informed consent for participation in human subject research emanates from the Nuremberg Code. *Permissible Medical Experiments*, in 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181-82 (1949). Today, human subject research is often governed by statute at the state and federal level. For instance, the Common Rule sets certain standards for human subject research conducted using federal funds. 45 C.F.R. § 46.101-.409 (2005).

²⁶ *Id.* at 787 (quoting Jon R. Waltz & Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 N.W.U. L. REV. 628, 640 (1970)).

subjects conducted using federal monies must comply with the Common Rule.²⁷ The Common Rule requires researchers to provide potential research participants with extensive information in the course of obtaining informed consent, including information about the expected risks and benefits of the research and confidentiality procedures to be followed, as well as assurance that participation is optional and may be withdrawn at any time.²⁸ The FDA imposes similar requirements for all studies submitted for its review.²⁹ Together, these two federal standards govern the vast majority of human subjects research conducted in the United States.

To date, agencies and courts have been hesitant to impose similar consent requirements on researchers obtaining human tissue for use in research, and human tissue research has therefore become a particularly thorny problem for traditional formulations of informed consent. In 2004, the federal Office of Human Research Protections issued a guidance document stating that “tissue collection for present or future research purposes is not subject to the IRB review and informed consent provisions of the Common Rule, as long as there is no personally identifiable information attached to the tissue specimens.”³⁰ In 2006, the FDA followed suit.³¹ In the famous *Moore* case, the California Supreme Court hinged John Moore’s ability to lodge a claim of lack of informed consent to the research and commercial use of his cells on the fact that his physician was acting in the role of both physician and researcher.³² However, whether researchers interacting with tissue providers in a purely research relationship owe any similar duty of care is

²⁷ See 45 C.F.R. §§ 46.101-46.124 (2006).

²⁸ *Id.* § 46.116.

²⁹ See 21 C.F.R. §§ 50, 56, 812 (2006).

³⁰ M. B. Kapp, *Ethical and Legal Issues in Research Involving Human Subjects: Do You Want a Piece of Me?*, 59 J. CLINICAL PATHOLOGY 335, 336 (2006).

³¹ 71 Fed. Reg. 1429 (Jan. 9, 2006) (providing notice that FDA “intends to exercise enforcement discretion when the study uses leftover specimens; . . . the specimens are not individually identifiable; the specimens are provided to the investigator(s) without identifiers . . . ; [clinicians are different people than researchers]; and the study has been reviewed by an IRB”).

³² *Moore v. Regents of the University of California*, 51 Cal. 3d 120, 129 (1990) (“(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.”).

less obvious. In *Greenberg*, for instance, the District Court stated, “[t]here is no automatic fiduciary relationship that attaches when a researcher accepts medical donations and the acceptance of trust, the second constitutive element of finding a fiduciary duty, cannot be assumed once a donation is given.”³³ The court in *Greenberg* held that the duty of informed consent could not be extended to require disclosure of a researcher’s commercial interests.³⁴ Indeed, that court expended considerable energy in deciding whether researchers have *any* duty to obtain informed consent from tissue providers.³⁵ Most recently, in *Catalona*, Judge Limbaugh eliminated all provider control over the use of tissue samples in a university repository by giving unrestricted ownership of the samples to Washington University and permitting “withdrawal” to be accomplished by anonymization, rather than removal from the repository.³⁶

In large part, these decisions are motivated by concern that demanding consent in the context of human tissue research will accrue to the detriment of scientific progress. Judge Limbaugh, for instance, declared in *Catalona*, “[m]edical research can only advance if access to these materials to the scientific community is not thwarted by private agendas.”³⁷ Likewise, in *Moore*, the California Supreme Court opined that recognizing Moore’s property right in his cells would have a chilling effect on socially beneficial medical research.³⁸ The FDA similarly asserted in its notice that “the existing [consent] requirements are bringing a halt to a class of very valuable

³³ *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1072 (S.D. Fla. 2003). *But see* *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001) (holding that “under certain circumstances, [informed consent agreements in nontherapeutic research projects] can, as a matter of law, constitute ‘special relationships’ giving rise to duties, out of the breach of which negligence actions may arise”).

³⁴ *Id.* at 1070-71.

³⁵ *Id.* at 1068-70. The court concluded that “in certain circumstances a medical researcher does have a duty of informed consent,” but it did not identify how one can identify when a duty does or does not attach. *Id.* at 1070.

³⁶ *Washington Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006). An appeal is pending.

³⁷ *Id.* at 1002.

³⁸ *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 143 (1990) (“The second important policy consideration is that we not threaten with disabling civil liability innocent parties who are engaged in socially useful activities, such as researchers who have no reason to believe that their use of a particular cell sample is, or may be, against a donor’s wishes.”).

research that can produce new diagnostic tests, without appreciably adding protection for human subjects.”³⁹

Yet, as Section II.A makes clear, enabling tissue providers to exercise their interests in the use of their cells in research is essential to the ethical and effective conduct of research. The same principles that under gird informed consent doctrine in the contexts of medical treatment and traditional human subjects research—including respect for autonomy and human dignity—support the need to obtain consent to the use of human tissue for medical research.⁴⁰ Moreover, instrumental interests in maximizing the amount of research-available tissue likewise point to giving teeth to consent in the context of human tissue research. Ultimately, both the interests of tissue providers and the interests of researchers must be accorded adequate respect and protection. If either set of interests is not properly attended to, the interests of both – as well as the interests of society at large – will be thwarted.⁴¹ Thus, policies regulating consent in the context of human tissue research must attempt to square ethics with practical and legal realities.

C. Models for Informed Consent for Human Tissue Research

In moving forward with human tissue research, three basic models of consent have developed. First, blanket consent may be obtained, in which potential tissue providers are asked to consent to all possible future research uses of their tissue. This model of consent is often preferred by administrators and regulators, as it imposes the fewest administrative burdens. For

³⁹ 1 Fed. Reg. 1429 (Jan. 9, 2006).

⁴⁰ See *supra* Section II.A; see also Russell Korobkin, *Autonomy and Informed Consent in Nontherapeutic Biomedical Research*, 54 UCLA L. REV. 605 (2007) (arguing that considerations of autonomy requires informed consent to the use of human tissue in medical research).

⁴¹ See Ted T. Ashburn, Sharon K. Wilson, & Barry I. Eisenstein, *Human Tissue Research in the Genomic Era of Medicine: Balancing Individual and Societal Interests*, 160 ARCHIVES INTERNAL MED. 3377, 3381 (2000) (noting that failing to mediate tensions between donors and researchers “may dissuade patients from participating in medical research studies and slow progress in medical research”).

example, following the royal assent of Canada's Assisted Human Reproduction Act,⁴² Health Canada, the body responsible for promulgating regulations pursuant to the Act, announced that it would require only blanket consent for individuals providing gametes for third-party assisted reproduction in Canada—once gametes are designated for third-party use, they come under the control of the gamete recipients, who may decide at a later date to allocate embryos created from those gametes to research purposes.⁴³ Blanket consent for research is also often obtained from patients at routine medical appointments. In many cases, physicians or hospitals “get consent with admission forms that say something like, *I give my doctor permission to dispose of my tissues or use them in research.*”⁴⁴

Many ethicists and legal scholars have rejected blanket consent models on grounds that they do not even approach true informed consent.⁴⁵ After all, human tissue research encompasses a broad range of activities, and tissue providers who wish to contribute to some research projects may not want to participate in others. Blanket consent therefore “impermissibly demands consent that may not be fully informed and that may oblige consent to research projects that are morally objectionable to some.”⁴⁶ As a general model of consent, blanket consent is overly broad.

At the other end of the spectrum is project-specific consent, under which tissue providers are contacted prior to each use of their tissues for research in order to provide the opportunity for consent. Project-specific consent best approaches the paradigm of informed consent, as it makes

⁴² Assisted Human Reproduction Act, 2004 S.C., ch. 2 (Can.).

⁴³ See Assisted Human Reproduction Section 8 Regulations, 139 C. Gaz. (Pt. I) § 13(d) (Sept. 24, 2005).

⁴⁴ Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES, Apr 16, 2006, at 38. The appropriateness of obtaining such consent in a general admission form (that many patients do not read) is debatable at best. However, given that Skloot reports that some physicians do not obtain even this limited consent, *id.*, some appreciation may be due to those physicians that make the limited effort to attempt to obtain consent of any kind for tissue donation.

⁴⁵ See, e.g., Clayton, *supra* note 7; Ram, *supra* note 4, at 23; Sade, *supra* note 8, at 1439. It is also worth noting that some authors have observed that blanket consent also does not meet the legal requirements of the Common Rule or HIPAA. See, e.g., Wendler, *supra* note 7.

⁴⁶ Ram, *supra* note 4, at 23.

available to tissue providers the most precise information for a given consent interaction. Because tissue providers consent to one research project at a time, they are necessarily more informed about the specific research projects in which their tissues are used. Nevertheless, although theoretically possible, project-specific consent has not been commonly used in the context of human tissue research because of its administrative burdens to researchers (for example, maintaining accurate phone or mail records and tracking tissue providers and their consent decisions)⁴⁷ and psychological burdens to tissue providers (continued confrontation with consent interactions can be stressful and bothersome for providers, especially when tissue was obtained in the course of treatment for illness).⁴⁸

Straddling the midpoint between blanket and project-specific consent is tiered consent, which attempts to preserve the benefits of blanket and project-specific consent models while minimizing their disadvantages. Tiered consent allows research participants to choose from a number of options, but does not oblige tissue providers to consent to any, some, or all categories of research. Furthermore, because tiered consent often includes an option for re-contact to obtain project-specific consent, tiered consent strengthens the ability of potential tissue providers to make their wishes known. In this respect, tiered consent protects consent as both freely given and informed.⁴⁹

At the same time, tiered consent often minimizes the administrative burdens associated with project-specific consent processes by standardizing the range of research categories to which

⁴⁷ See P.N. Furness & M.L. Nicholson, *Obtaining Explicit Consent for the Use of Archival Tissue Samples: Practical Issues*, 30 J. OF MED. ETHICS 561 (2004).

⁴⁸ See PEOPLE SCI. & POL'Y LTD., BIOBANK UK: A QUESTION OF TRUST: A CONSULTATION EXPLORING AND ADDRESSING QUESTIONS OF PUBLIC TRUST (2002), available at <http://www.ukbiobank.ac.uk/docs/consultation.pdf>.

⁴⁹ The legal status of tiered consent is not uncontroversial. For instance, although the National Bioethics Advisory Commission recommended tiered consent for obtaining consent to future use of tissues in research, some commissioners expressed concerns that tiered consent may not meet legal thresholds for disclosure. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 1, at 65. To date, no complete and rigorous analysis of the legal status of tiered consent has been completed.

tissue providers may consent and obtaining this consent upfront, rather than continually as research projects arise. Tiered consent thus assuages many of the concerns identified by courts and regulators declining to impose consent requirements on those obtaining tissue for research purposes.⁵⁰

Yet, in attempting to ensure adequate provider choice while limiting administrative and researcher burdens, tiered consent is also a process constantly in tension. The ethical (and sometimes legal) demands of true informed consent exert pressure towards continually expanding menus of research categories to which potential tissue providers may consent. More research options, each of which embraces a narrower range of research projects, would seem to increase the probability that a given tissue provider truly understands and shares in the nature and goals of the research to which she is consenting. Insofar as autonomy, understood in rational choice terms, is a guidepost to informed consent theory and doctrine, proliferation of tiered consent options is likely to be demanded. Tiered consent thus represents a delicate balance between the competing but interdependent interests of tissue providers on the one hand (who might otherwise demand more information and more research categories among which to choose) and the interests of researchers on the other hand (who might otherwise desire fewer restrictions on access to tissues).⁵¹

Tiered consent is most frequently encountered in cancer research, where tumor tissue plays a key role in research to understand how cancer develops and progresses and to develop new treatments. Patients undergoing biopsy or surgery are routinely asked to provide their excised

⁵⁰ See *supra* notes 37-39 and accompanying text.

⁵¹ In this sense, one might view tiered consent as analogous to intellectual property rights like copyright, which also seek to maintain a “delicate balance” among two interdependent and competing groups of interests in free expression. See David Nimmer, Elliot Brown, Gary N. Frischling, *The Metamorphosis of Contract into Expand*, 87 CAL. L. REV. 17, 22 n.9 (1999) (describing the widespread metaphor of copyright as a “delicate balance”).

tissues for research purposes. Consent for such provision often takes the form of tiered consent presenting three options:

1. My tissue may be kept for use in research to learn about, prevent, or treat cancer.
2. My tissue may be kept for use in research to learn about, prevent or treat other health problems (e.g., diabetes, Alzheimer's disease, or heart disease).
3. Someone from xyz may contact me in the future to ask me to take part in more research.⁵²

However, in a recent report that displays the tensions seemingly inherent in formulating tiered consent processes, the Tissue Access Working Group of the National Dialogue on Cancer Research has questioned whether this consent model “go[es] far enough” in protecting patient choice.⁵³ The Working Group identified several additional parameters along which patient/provider choice could be expanded, including type of sample, type of research (parsed more finely than in the current form), type of specimen to be provided, type of researcher, duration of storage time, and type of products, if any, to be derived from the tissue.⁵⁴

Proposals for tiered consent for other types of research have also appeared. For example, I have proposed elsewhere a model for tiered consent for individuals providing gametes for third-party use that would preserve the ability of such providers to control whether embryos created using their gametes would be eligible for research use and, if so, for what kinds of embryo research.⁵⁵ Drawing on categories of embryo research identified in British legislation, this model

⁵² *What Is Tiered Consent?* (Dec. 27, 2005), <http://www.usm.maine.edu/bioethics/biobank/ethical/ic/tiered.html> (listing the options in the model consent form of the Tissue Access Working Group for consent to tissue donation to National Cancer Institute databases).

⁵³ *Id.*

⁵⁴ *Id.*; see also EISEMAN ET AL., *supra* note 4, at 134.

⁵⁵ Ram, *supra* note 4, at 24.

for tiered consent suggested at least eight potential research categories. More generally, the National Bioethics Advisory Commission has also advocated the adoption of tiered consent processes for human tissue research, although no precise number of research categories was identified.⁵⁶

As research progresses and expands, the number of substantively and ethically diverse uses for human tissue in research likewise expands. Human embryos may be used to develop more efficient techniques of *in vitro* fertilization, or safer abortifacients, or embryonic stem cell lines that may serve as the substrate for research wholly unrelated to reproduction. The same is true for other kinds of tissue research—cancer tissue, for instance, may now be cultivated into stem cell lines that can be directed toward a host of research projects beyond anything contemplated even in the recent past. As noted above, if consent is to be truly informed, this would seem to demand that the number of research categories in tiered consent processes must also expand. The Tissue Access Working Group's proposal for expanded choice in tiered consent processes for research use of cancer tissue is real world evidence of the concern that expanding avenues of research requires expanding tiered consent menus.

Yet, beyond a certain point, more choice may frustrate informed decision-making, rather than aid it. If regulations governing research and judicial doctrines imposing liability for faulty procedures are to engender processes that permit potential research participants to make free and informed choices about providing their tissues for research purposes, it is essential that policymakers understand and incorporate findings about the dynamics of decision-making in constructing appropriate consent processes.

III. THE PSYCHOLOGY OF DECISION-MAKING IN SITUATIONS OF ABUNDANT CHOICE

⁵⁶ NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 1, at 64-65.

Traditional social science theory suggests that more choices are preferable to fewer choices: “[T]he standard line among social scientists who study choice [is that i]f we’re rational . . . added options can only make us better off as a society.”⁵⁷ For those who want just the “right” thing, more choice means a greater probability of success. Alternatively, for those who do not really care one way or another, all the additional choices can simply be ignored.

In general, this logic seems compelling. It is obvious, after all, that having choices improves our quality of life: “It enables us to control our destinies Choice is essential to autonomy, which is absolutely fundamental to well-being. Healthy people need and want to direct their own lives.”⁵⁸ This is precisely the understanding of autonomy and liberty that under girds the traditional doctrine of informed consent.

Yet, social science researchers are discovering that “the fact that *some* choice is good doesn’t necessarily mean that *more* choice is better.”⁵⁹ Such findings are antithetical to classic economic theory because this theory does not admit to limitations in human cognition or to potential psychological tradeoffs that must be made when many as opposed to few options are available. The rise of behavioral economics and decision-making psychology, meanwhile, is beginning to draw attention to precisely these tradeoffs. Indeed, researchers in these fields are finding that more choice can actually demotivate decision-making and decrease satisfaction and happiness when choices are made.

⁵⁷ BARRY SCHWARTZ, *THE PARADOX OF CHOICE* 19 (2004).

⁵⁸ *Id.* at 3; *see also* EDWARD L. DECI & RICHARD M. RYAN, *INTRINSIC MOTIVATION AND SELF-DETERMINATION IN HUMAN BEHAVIOR* (1985); GREGG EASTERBROOK, *THE PROGRESS PARADOX* (2003) (arguing that the standard of living in modern America far exceeds that of almost all people throughout human history); Diane I. Cordova & Mark R. Lepper, *Intrinsic Motivation and the Process of Learning: Beneficial Effects of Contextualization, Personalization, and Choice*, 88 *J. OF EDUC. PSYCHOL.* 715 (1996); Sheena S. Iyengar & Mark R. Lepper, *When Choice is Demotivating: Can One Desire Too Much of a Good Thing*, 79 *J. OF PERSONALITY & SOC. PSYCHOL.* 995 (2000) (documenting several books and journal articles demonstrating that provision of choice can be positive).

⁵⁹ SCHWARTZ, *supra* note 57, at 3.

This Part focuses on the implications of hyper choice for decision-makers. The Part that follows then explores what effect these implications are likely to have in the context of informed consent using a tiered model. Current research suggests four primary pitfalls to abundant choice: information overload; arbitrary selection; avoidance of decision-making; and regret. Each of these will be discussed in turn.

A. *Information Overload*

Data on the effects of consumer hyperchoice and information overload first surfaced in the 1970s and 1980s.⁶⁰ These studies showed that the human brain is not of limitless capacity and that the information available for decision-making can only be of some finite magnitude before the mind is simply overwhelmed. Defining “information load” as “a multiplicative function of the amount of product attributes and alternative information available for a single decision,”⁶¹ these researchers and their modern counterparts have identified two axes along which information overload can occur. First, decision-makers experience information overload when presented with an overwhelming number of options that must be considered simultaneously. Second, decision-makers experience information overload when presented with an overwhelmingly complex decision, even when only a few options are available, due to the many details or attributes of each option that need to be considered. Most research on the constraints of information load has focused on the former problem, and, moreover, most of this research has focused on decision-making by consumers in a market setting.

⁶⁰ See, e.g., Jacob Jacoby, *Information Load and Decision Quality: Some Contested Issues*, 14 J. OF MARKETING RES. 569 (1977); Naresh K. Malhotra, *Information Load and Consumer Decision Making*, 8 J. OF CONSUMER RES. 419 (1982); William M. Wilkie, *Analysis of Effects of Information Load*, 11 J. OF MARKETING RES. 462 (1974).

⁶¹ David Glen Mick, Susan M. Broniarczyk, & Jonathan Haidt, *Choose, Choose, Choose, Choose, Choose, Choose, Choose: Emerging and Prospective Research on the Deleterious effects of Living in Consumer Hyperchoice*, 52 J. OF BUS. ETHICS 207, 208 (2004).

When individuals experience information overload, research suggests that they adopt a variety of methods for simplifying the decision-making process. For instance, decision-makers adopt “simplifying rules”⁶² or rely on “simple heuristics,”⁶³ discarding or ignoring a great deal of available information and focusing instead on a manageable subset of characteristics—in other words, they essentialize. This behavior has been shown to lead to lower quality decision-making in situations where there were clearly superior options given the benefits available for the price charged.⁶⁴ Alternatively, some studies have suggested that as the number of options and the information about those options increases, decision-makers often consider only a small subset of the total choices available.⁶⁵ This means that decision-makers exclude a broad range of options without really evaluating them, once again an outcome likely to lead to lower quality decision-making.

Notwithstanding these data, some scholars have advanced the view that the use of heuristics can, in some situations, lead to more accurate decision-making.⁶⁶ Among the most well known of these fast and frugal decision-making techniques is the Take the Best heuristic. Take the Best, when modeled on a computer, is used to arrive at an answer simply and easily. Even where multiple types of relevant information to decision-making are provided, a system running Take the Best will consider only one criterion of information at a time—starting with the criterion with the highest validity, or relative frequency with which the given criterion will identify the right answer.⁶⁷ If, on the basis of that single factor alone, one possible answer is indicated, this answer will be adopted, and the remaining criteria will never be considered. If the initial factor does not

⁶² *Id.*

⁶³ Iyengar & Lepper, *supra* note 58, at 996.

⁶⁴ Mick, Broniarczyk & Haidt, *supra* note 61, at 208.

⁶⁵ John R. Hauser & Birger Wernerfelt, *An Evaluation Cost Model of Consideration Sets*, 16 J. OF CONSUMER RES. 393 (1990).

⁶⁶ See generally SIMPLE HEURISTICS THAT MAKE US SMART (Gerd Gigerenzer et al. eds., 1999).

⁶⁷ Gerd Gigerenzer & Peter M. Todd, *Fast and Frugal Heuristics: The Adaptive Toolbox*, in SIMPLE HEURISTICS THAT MAKE US SMART, *supra* note 66, at 80.

make an answer plain, the criteria with the next highest validity will be tested—alone—and so on, until an answer is indicated.⁶⁸ The key to Take the Best is that each criterion of information is tried independently; information learned from one criterion is not retained when the next criterion is tested. Take the Best adopts as its motto “take the best, ignore the rest.”⁶⁹ In the real world, Take the Best might operate when, faced with massive amounts of information, we simply ignore the vast majority of available information in favor of focusing on one or two key and manageable criteria.

In studies comparing the accuracies of Take the Best and regression analysis (which integrates a large amount of information in arriving at a decision) at predicting which of two cities is larger, the fast and frugal heuristic was able to predict city size with nearly as much, and in some cases more, accuracy than the more complicated and time consuming regression analysis.⁷⁰ In these studies, ten criteria, such as whether the city had a soccer team or a university, were available for analysis.⁷¹ Multiple regression analysis, which integrated and considered all ten variables, identified the larger of two cities with 65.7 % accuracy.⁷² Meanwhile, Take the Best, which considered only three criteria, made accurate choices 65.8 % of the time.⁷³ These data have led some researchers to laud these heuristics as critical to human survival and far from detrimental to functional decision-making in many contexts.

B. Checking Out: Of Jams and Exams

⁶⁸ *Id.* at 81.

⁶⁹ *Id.*

⁷⁰ *Id.* at 87-88.

⁷¹ *Id.* at 85.

⁷² *Id.* at 87.

⁷³ *Id.*

Hyperchoice conditions and the difficulties of information overload can lead not only to essentializing, but also to efforts to “check out” of the decision-making process altogether. Available research points to two ways in which individuals experiencing information overload attempt to escape decision-making. In some cases, where the number of available choices is so great as to be “truly daunting,” rather than trying to choose, “people may disengage, *choosing almost arbitrarily* to complete the process.”⁷⁴ In other cases, where individuals have an option not to participate in decision-making at all, they will do so, opting instead for the status quo. In a third, distinct pattern, research suggests that sequential decision-making is psychologically fatiguing and that later-made decisions are likely to be more arbitrary or oriented towards the status quo.

“Opting out” has been demonstrated recently in a series of studies involving the purchase of exotic jams in a grocery store and the successful completion of an extra-credit assignment by college students in an introductory social psychology course.⁷⁵ In the first study, shoppers at an upscale grocery store encountered booths offering free sampling of Wilkin and Sons jams. The booths varied in whether they offered six jams for tasting (the limited choice condition) or twenty-four (the extensive choice condition). Each participant could sample as many of the available jams as desired. Following tasting, each participant was given a coupon to save one dollar on the purchase of a Wilkin and Sons jam. Shoppers interested in purchasing jams did so from the regular jam aisle, where they encountered all available varieties of Wilkin and Sons jams (as well as jams from other brands). The results were startling. Although more people initially approached the extensive choice booth to participate in sampling of jams (sixty percent of those who passed the extensive choice booth stopped, while only forty percent of passing

⁷⁴ Barry Schwartz et al., *Maximizing Versus Satisficing: Happiness Is a Matter of Choice*, 83 J. OF PERSONALITY & SOC. PSYCHOL. 1178, 1779 (2002) (emphasis added).

⁷⁵ Iyengar & Lepper, *supra* note 58.

shoppers stopped at the limited choice booth; $\chi^2 (1, N = 502) = 19.89, p < 0.001$), far more individuals who had visited the limited choice booth subsequently purchased jams (thirty percent of limited choice participants versus only three percent of extensive choice samplers; $\chi^2 (1, N = 249) = 32.34, p < 0.0001$).⁷⁶ The researchers concluded that although extensive options may at first appear more appealing than a limited array of options, “having ‘too much’ choice seems nonetheless to have hampered [participants’] later motivation to buy.”⁷⁷ In others words, when faced with choosing among a larger number of options, more individuals opted simply to make no selection at all.

In the second study, students in an introductory social psychology class were presented with the opportunity to submit a two-page essay as an extra-credit assignment. Student sections were provided with either a list of six potential essay topics (the limited choice condition) or a list of thirty topics from which to choose (the extensive choice condition). The results again were striking. Students with the limited choice list were more likely not only to submit extra-credit essays than students faced with the extensive choice list (seventy-four versus sixty percent completion; $\chi^2 (1, N = 193) = 3.93, p < 0.05$), but also to perform slightly, but significantly, better on those essays than extensive choice students (graded on a ten-point scale, limited choice writers scored on average 8.09 points, while extensive choice writers scored only 7.69 points; $F(1, 124) = 5.65, p < 0.02$).⁷⁸ Again, these results confirmed that facing extensive options “does not necessarily lead to enhanced motivation when compared with contexts that offer a limited array of options.”⁷⁹ Moreover, student scores demonstrated that among active participants (i.e.,

⁷⁶ *Id.* at 997.

⁷⁷ *Id.*

⁷⁸ In addition to the statistical tests conducted and reported in the study, a t-test statistic, measuring the statistical significance of differences in the mean values between two groups may be helpful. Having conducted a t-test, the results show that the differences in average grades in study 2 between limited choice and extensive choice participants is statistically significant ($p < 0.01$).

⁷⁹ Iyengar & Lepper, *supra* note 58, at 999.

essay writers), individuals in limited choice settings tend to outperform those in extensive choice settings. Indeed, Iyengar and Lepper reported that even where students in the two groups selected the same essay topic, students in the extensive choice group performed worse than those in the limited choice group.⁸⁰

These studies suggest not only that individuals experiencing information or choice overload tend to avoid decision-making by opting out of active participation, but also that when they do participate they tend to do less well. Iyengar and Lepper suggest that this second finding may result because individuals in hyperchoice situations adopt simplifying heuristics for decision-making. Choice mediated through such simplifying heuristics may “lead[decision-makers] to feel less committed to exercising their preferences.”⁸¹

Finally, a separate study examining the effects of sequential decision-making also suggests that decision-makers tend to opt out of making decisions when overwhelmed. One study found that after making an initial difficult decision, individuals faced with another difficult decision were more likely to opt for the status quo and other risk-averse options.⁸² Another study documented that after making binary choices across different product classes, participants who had made numerous choices were significantly less able to persist at an unsolvable puzzle or to force themselves to continue drinking a distasteful beverage than the control group.⁸³ These results strongly suggest that making difficult decisions is strenuous and fatiguing, and that the making of multiple and sequential decisions leads to declining willpower and informed decision-making.

⁸⁰ *Id.* (“The condition effect was . . . significant for [overall grade], $F(1, 124) = 5.65, p < .02$, with students in the limited-choice condition receiving higher grades ($M = 8.09, SD = 1.05$) than those in the extensive-choice condition ($M = 7.69, SD = 0.82$).”).

⁸¹ *Id.*

⁸² Mick, Broniarczyk, & Haidt, *supra* note 61, at 208 (discussing a study by Jason Riis and Norbert Schwarz).

⁸³ *Id.* at 208-09 (discussing Roy Baumeister & Kathleen Vohs, *Willpower, Choice, and Self-Control*, in *TIME AND DECISION: ECONOMIC AND PSYCHOLOGICAL PERSPECTIVES ON INTERTEMPORAL CHOICE 201* (George Loewenstein, Daniel Read, & Roy F. Baumeister, eds., 2003)).

C. Regret

A third trend in findings on the implications of hyperchoice is that individuals making decisions in hyperchoice settings tend to experience more frustration in decision-making and more regret afterwards. For instance, in analyzing the extra-credit essay writing results, Iyengar and Lepper hypothesized that “choosers in extensive-choice contexts . . . may feel more responsible for the choices they make because of the multitude of options available.”⁸⁴ That is, given more options, individuals may feel more pressure to find the “best” one and are more likely to fear or experience regret once they have made a decision. Fear of regret, in turn, may cause individuals to refrain from choosing one option among many—once again, opting out of decision-making.

To test whether regret or fear of regret influences decision-making, Iyengar and Lepper devised a study in which individuals were asked to select a Godiva chocolate that they would buy for themselves based on name and appearance alone. Participants were presented with either six or thirty options. Participants were then given the opportunity to taste a chocolate. Some groups were not given a choice about which chocolate to taste; the remaining groups were offered the chance to sample the chocolate they had indicated previously. Finally, all participants were presented with two different compensation mechanisms: either five dollars in cash or a box of Godiva chocolates worth five dollars.

The results of this study showed that individuals given extensive choices found the decision-making process to be both more enjoyable and more frustrating than individuals in either the limited choice or no choice setting.⁸⁵ In measuring satisfaction following decision-making,

⁸⁴ Iyengar & Lepper, *supra* note 58, at 1000.

⁸⁵ *Id.* at 1002.

Iyengar and Lepper found that participants in the extensive choice condition were significantly less satisfied with their sampled chocolates than were participants in the limited choice condition, although both of these groups reported higher satisfaction than those in the no choice condition.⁸⁶

Barry Schwartz and colleagues tie regret to individuated decision-making approaches. Schwartz and colleagues posit that there are two types of decision-makers: maximizers, who always seek the “best” option, and satisficers, who generally seek a “good enough” option.⁸⁷ While having more choices may mean that maximizers are more likely to find just the right product or to make just the right choice, having more choices also means that there is a greater risk of not choosing the best option. If a better option later becomes available or apparent (or perceived), maximizers are likely to experience regret. Maximizers may be more likely to avoid making decisions in the first place, in order to minimize the opportunity for making a “wrong” decision. Satisficers, meanwhile, are less likely to be distressed if a better option subsequently appears because of their orientation towards “good enough” options rather than “best” ones. Therefore, satisficers are less likely to experience regret and less likely to opt out of decision-making, even when choices are abundant.

IV. ABUNDANT CHOICE AND TIERED CONSENT

Despite the intermittent references of several authors to medical decision-making and hyperchoice,⁸⁸ the vast majority of available research in this emerging field focuses on consumer psychology in which a prospective buyer must choose one product out of a large number of

⁸⁶ *Id.* at 1003.

⁸⁷ Schwartz et al., *supra* note 74, at 1179.

⁸⁸ See, e.g., Barry Schwartz, *The Tyranny of Choice*, SCIENTIFIC AMERICAN, Apr. 2004, at 70, 74; Iyengar & Lepper, *supra* note 58, at 1004.

similar products. In the tiered consent context, conversely, each option represents a possible research choice, but all, some, or none of these options may be selected simultaneously. Thus, where the problems of hyperchoice result from an inability to accurately weigh opportunity costs, such problems may not arise for potential tissue providers facing tiered consent because the opportunity cost of providing tissue to option *A* rarely includes an inability to provide tissue to option *B*. This seems most salient in considering the effects of regret on decision-making. After all, if one is concerned about the possibility that *B* will turn out to be better than *A*, then the ability to select both *A* and *B* limits the possibility of missing out on the “best” choice.

However, there are good reasons to believe that the problems experienced in consumer hyperchoice may also manifest themselves in tiered consent hyperchoice. This Part applies the findings of consumer choice psychology identified in Part III to tiered consent, demonstrating that the difficulties of consumer hyperchoice are likely to occur with as much or more effect in the high stakes context of providing tissue for research as in the context of the grocery store.

A. Information Overload

Research finding that individuals faced with information overload tend to ignore a great deal of available information or a number of available options is distressing for those concerned with informed decision-making. Informed consent, after all, focuses not only on disclosure of relevant information, but also on a potential tissue provider’s competency and ability to understand and make use of that information. In the tiered consent context, if the number of available options is overwhelming, potential tissue providers may unconsciously choose to ignore several options, depriving them of the opportunity to provide tissue to research they may find enriching upon closer inspection. Alternatively, potential tissue providers may attempt to choose among a vast

array of options by adopting an essentializing heuristic and thereby ignoring swaths of relevant and important information about each option, which could lead to truly uninformed decision-making.

Tiered consent may also be a source of information overload not only through offering too many options to be simultaneously considered, but also by virtue of the fact that the decision to be made is likely to be a complex one. Most tissue providers are not medically or scientifically trained, and this limits their ability to grasp subtle nuances in scientific methodologies, to consider the broad range of research for which they may be providing their tissues, or to understand the tradeoffs implied in selecting one set of research options over another. The disclosure of a vast quantity of information, even about a limited set of available options, may therefore be a disservice to potential tissue providers, if it causes decision-makers to ignore a great deal of that information and therefore to make less informed decisions.⁸⁹

For example, in the United States, human oocytes may be donated (or bought) for research purposes.⁹⁰ Because oocytes are a finite resource, their allocation to one research use necessarily reduces the number of eggs available for other research purposes. This is especially so with respect to embryonic stem cell research, which is a highly inefficient process at present.⁹¹ Thus, it is critical that potential oocyte providers understand each option independently so that they are

⁸⁹ The same may hold true for disclosure of information in the medical treatment setting, wherein there is strong legal incentive for physicians to disclose *all* available information as a shield to liability.

⁹⁰ At present, there is no federal law banning the sale or donation of human oocytes (eggs) for research purposes, although no federal funds may be used in connection with any research on human embryos and funding is only available for a limited number of human embryonic stem cell lines. See President's Address to the Nation on Stem Cell Research, 37 PUB. PAPERS 32 (Aug. 9, 2001). Some states have enacted legislation that governs assisted human reproduction that may govern access to donor eggs. Moreover, the National Academies has issued ethical guidelines for human embryonic stem cell research that recommended that gamete donors be compensated only for expenses and not for their eggs or sperm directly. See Amy Adams, *Guidelines Issued for Embryonic Stem Cell Research*, STANFORD REPORT, Apr. 27, 2005, <http://news-service.stanford.edu/news/2005/april27/med-stemcell-042705.html>. However, these guidelines are optional and do not have force of law.

⁹¹ Stem cell derivation from human embryos succeeds roughly thirty-five percent of the time. See Lisa M. Hoffman & Melissa K. Carpenter, *Characterization and Culture of Human Embryonic Stem Cells*, 23 NATURE BIOTECHNOLOGY 699, 700 tbl.1 (2005). Percentage was obtained by averaging values reported in "percentage of cell lines from ICMS."

best able to allocate their oocytes in accordance with their values. Indeed, informed consent doctrines and regulations must be designed to create processes that permit potential tissue providers to make choices according to their values—this is the core of the autonomy/human dignity norm of informed consent.⁹² In cancer research, patients providing their tissue “for use in research to learn about, prevent or treat other health problems”⁹³ may not understand just how broad a range of research projects this provision may encompass—“other health problems” may include Alzheimer’s research, but may also include research directed at deriving stem cell lines and learning how to differentiate stem cells into specialized cell types.

In the context of consent, it is critical that all relevant information be processed and integrated so that decisions are maximally informed. This must be true for each option in a tiered consent menu. Excluding options from consideration or employing essentializing decision-making heuristics to exclude certain data about each option undermines the purposes of tiered consent and consent in general. Policymakers, ethicists, and researchers charged with designing informed consent processes must recognize and respond appropriately to this kind of limitation in human cognition and understanding, so that tiered consent processes serve, rather than undermine, the goals of informed consent.

Moreover, while the success of fast and frugal heuristics like Take the Best might suggest that adopting heuristics does not undermine the ability of tissue providers to make choices consistent with their values, there is good reason to believe that the demonstrated success of these heuristics does not correlate with usefulness in informed consent. In the first instance, it is not at all clear that individuals have fixed preferences among different decision-making variables (fixed criteria validity) in the technical arena of medical decision-making, nor is there any

⁹² See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972) (“True consent to what happens to one’s self in the informed exercise of a choice . . .”).

⁹³ *What Is Tiered Consent?* (Dec. 27, 2005), <http://www.usm.maine.edu/bioethics/biobank/ethical/ic/tiered.html>.

objectively “right answer” when it comes to providing tissue for research. Furthermore, the studies cited throughout Part III indicate that hyperchoice settings are particularly ill suited for accurate decision making by fast and frugal heuristics. Indeed, some studies have shown that information overload and reliance on heuristics lead to lower quality decision-making in situations where objectively superior options exist.⁹⁴ More specifically, research shows that lower quality decision-making is especially likely to occur when the decision to be made demands emotional or manual investment from the decision maker. For example, when students were provided with either limited or extensive numbers of choices for extra credit essays, individuals in the limited choice setting outperformed those in the extensive choice setting, even when students selected the same essay topic.⁹⁵ As Iyengar and Lepper noted, choice mediated through simplifying heuristics may “lead[decision-makers] to feel less committed to exercising their preferences.”⁹⁶

Providing tissue for medical research is likely to be an arena in which decision-making is, in fact, emotionally or manually demanding, especially for certain kinds of tissues. Unlike consumer goods, in which having a stereo, for instance, is clearly a good, tissue provision is not always so clear. For example, providing human eggs or embryos is not such an unqualified good. Some individuals feel strongly that no human embryo research should be conducted. Others feel that although embryo research on the causes and treatment of infertility is valuable, embryo research to develop abortifacients or embryonic stem cell lines is morally reprehensible. Even those who find embryo research of all kinds morally neutral may experience moral anxiety in egg or embryo donation simply because it brings to the forefront their lack of moral engagement with an issue that is so morally relevant for most others. Thus, tiered consent procedures that

⁹⁴ See, e.g., Mick, Broniarczyk & Haidt, *supra* note 61, at 208.

⁹⁵ Iyengar & Lepper, *supra* note 58, at 999.

⁹⁶ *Id.*

encourage or demand the adoption of decision-making heuristics are likely to disserve potential tissue providers by alienating them from a true possibility of making choices according to their interests, and this disservice is only exacerbated as the emotional or moral stakes of tissue provision increase.

B. Checking out

Again, results showing that individuals in situations of hyperchoice attempt to “check out” of decision-making and perform less well when decisions are made are troubling in thinking about informed consent and tiered consent models. According to these research results, presenting potential tissue providers with more options to which they may consent is likely to lead to less informed decision-making if potential tissue providers arbitrarily select options in a tiered consent menu or attempt to opt out of making a decision by checking a blanket consent option. Alternatively, hyperchoice in tiered consent could lead to less tissue overall being provided for research, as potential tissue providers choose to opt out of providing tissue altogether because the prospect of decision-making is too overwhelming. These behavior patterns appear especially likely to manifest in contexts like tiered consent, in which the highly technical nature of medical research and the relative inability for the ordinary tissue provider to understand the nuances of proposed research categories coincide with a potentially large number of categories about which to process information.

The results on sequential decision-making are particularly significant. Tiered consent demands sequential decision-making because tissue providers are permitted and encouraged to consider providing tissue to multiple types of research and therefore choosing one research option does not necessarily exclude selection of all others. Indeed, because each option

represents an independent opportunity to provide tissue for research, tiered consent is more likely than consumer hyperchoice to present difficulties associated with sequential decision-making. Most studies on sequential decision-making track numerous binary (yes/no) choices—precisely the type of decision-making that occurs in tiered consent. Evidence of psychological fatigue leading to less informed decision-making suggests that even where tissue providers strive to make informed decisions, they may simply be psychologically incapable of doing so in the repeated iterations required for extensive tiered consent.

None of these outcomes is desirable—from either an informed consent or an efficient research perspective. Opting out and arbitrary selection brought about by hyperchoice obfuscate the basic purpose of offering tiered consent, which is permitting tissue providers to exercise control over the destiny of their tissue (and, more specifically, their genetic material) while minimizing administrative monitoring costs. More generally, consent theory and doctrine are concerned with the design of processes that facilitate informed choice, and therefore both uninformed authorization and uninformed refusal are problematic.

C. Regret

Finally, findings regarding patterns of regret in decision-making are significant in the context of consent. These patterns of regret matter to evaluation of informed consent processes because regret, or fear of regret, may lead to opting out of decision-making. As observed above, opting out undermines the purposes of informed consent generally and the delicate balance between control and efficiency sought in tiered consent in particular.

Regret is likely to appear with greater force in the context of tiered consent than in settings of consumer choice. Findings on regret show that extensive choice can be demotivating when the

decision to be made is a trivial one—whether to buy jam, write an extra-credit essay, or accept chocolates rather than cash as compensation. When the stakes of decision-making are higher, as in the provision of tissues for research purposes, the possibilities for regret are likewise greater. Indeed, Iyengar and Lepper identify medical decisions as those that are likely to exacerbate the demotivating effects of hyperchoice, as these are decisions “in which . . . the costs associated with making the ‘wrong’ choice, or even beliefs that there are truly ‘wrong’ choices, are much more prominent, and/or . . . substantial time and effort would be required for choosers to make truly informed comparisons among alternatives.”⁹⁷ In other words, while abundant choice alone may be sufficient to trigger reactions of regret in decision-making, these reactions are amplified as decision-making is laden with emotional or moral weight.

As noted in Section IV.A, providing eggs and embryos for research, for example, is often fraught with moral significance, and tissue providers may have strong opinions about different types of embryo research. Even for those who view egg and embryo provision and related research as morally neutral, the consent/provision process—the need to think about what research projects constitute ethical egg and embryo research—may be emotionally burdensome. The act of providing these traditionally “special” tissues for research may bring about feelings of moral inadequacy, a sense that “I ought to care more (and if I don’t, what’s wrong with me?).” Yet, egg and embryo research is not unique in its moral valence. Individuals may hold strong views about the ethics of commercial research, especially where research may lead to the production of pharmaceutical or other products that they and others may not be able to access due to limited financial resources. Tissue providers of all kinds may also feel morally implicated where their genetic material is utilized in the hunt for certain kinds of genetic relationships—for example, between sex and spatial reasoning skills or between race and intelligence. Because cells

⁹⁷ Iyengar & Lepper, *supra* note 58, at 1004.

from any part of the body may be used in these kinds of research projects, these concerns apply equally to human embryos, excised cancer tissue, and routine blood samples. While the government may not be able to prohibit these kinds of genetic studies from going forward,⁹⁸ surely private individuals should be permitted to make their strongly held preferences known and to have those preferences respected.

Regret in hyperchoice decision-making may turn not only on the moral weight accorded to the decision, but also on the nature of the decision and relationship between the choices offered. For some tissues, selecting *A* may in fact effectively preclude selecting *B*, *C*, and *D*, simply because the tissue in question (e.g., human eggs) is a finite and discrete resource. Alternatively, regret may result as much from trying to do too much as from trying to select one item among many. Regret in these instances may manifest as a result of sequential decision-making, with its attendant increasing fatigue and psychological strain.⁹⁹ In this vein, one researcher notes that our multiple consumer obligations—more choices, but less time—“may not contribute as much as quality of life as once thought or hoped for.”¹⁰⁰ This suggests that anguish in decision-making does not arise solely from the opportunity costs of giving up other options, but may also result from trying to take part in too many opportunities at the same time. As tiered consent is informed by commitments to autonomy and control in order to afford tissue providers with favorable conditions for allocating tissues in accordance with their values, the psychology of regret threatens to cause tissue providers, once again, either to opt out of such provision altogether or to experience negative reactions to the consent/provision process.

⁹⁸ See, e.g., Richard Delgado et al., *Can Science Be Inopportune? Constitutional Validity of Governmental Restrictions on Race-IQ Research*, 31 UCLA L. REV. 128, 160-63 (1983); John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1212-14 (1978).

⁹⁹ See *supra* Sections III.B and IV.B.

¹⁰⁰ Mick, Broniarczyk & Haidt, *supra* note 61, at 207.

Thus, emerging research about the implications of hyperchoice and the psychology of decision-making suggest definite and significant limits for both the number of options available in a tiered consent menu and the amount of information that potential tissue providers can process about each option. Additionally, in some instances these findings seem to bear more heavily on some kinds of tissue research than on others. For instance, providers of human eggs and embryos may experience fewer difficulties arising from sequential decision-making owing to the fact that these tissues are more likely to be finite research resources. Yet, these providers may experience greater difficulties arising from classic consumer choice problems (they may be unable to provide tissue for every category of research they deem worthwhile), as well as possibly greater moral unease about providing reproductive tissue for research of different kinds. Alternatively, while providers of cancer tissue or blood samples may be able to supply sufficient tissue for any and all research categories they find worthwhile, these individuals will face greater stress arising from sequential decision-making.

In all of these instances, findings that information overload causes decision-makers to opt out of decision-making, to make less informed decisions when they participate, and to experience greater feelings of regret over decision-making make clear that information dumping is inconsistent with the principles underlying the doctrine of informed consent. Despite current medical practices to disclose any and all information as a shield to liability (and the greater legal imperative to disclose in the context of research), presenting potential tissue providers with a large number of options, or excessive information about these options, may lead to consent procedures that are less, rather than more, worthy of legal and ethical support. Tiered consent, while very likely a best practice for human tissue research, must be designed with full

cognizance of and appreciation for the limitations of the human mind in order to better facilitate decision-making that is truly informed and freely given.

VI. CONCLUSION

As human tissue research proliferates, research institutions and biorepositories, and those crafting the policies that govern these entities, will face increasing pressure to make more tissue available for more projects. Meanwhile, those concerned with ensuring informed consent will surely press for enhanced protection for those providing tissue for research, such as the inclusion of more research categories in existing tiered consent forms to approximate better the traditional informed consent model. Somewhere along this spectrum, legislators, agencies, and courts will have to carve out reasonable policies that respect the interests of both tissue providers and researchers. At the very least, this charge demands a change in existing standards to include, rather than exempt, human tissue research from the range of activities to which the legal rules and doctrines governing human subjects research apply. Moreover, in an effort to strike a balance between competing interests in ethical conduct and efficient research, policymakers should affirmatively encourage or mandate tiered consent as a best practice. The precise details of what tiered consent should contain must be informed by findings about cognitive limitations leading to lower quality decision-making, checking out, and regret in situations of hyperchoice. While a specific number or description of categories is premature at this time (and must await future research), the implications of consumer psychology for tiered consent and abundant choice stand as a stark caution sign that increasing providers' options will not always create correspondingly greater provider control.

Barry Schwartz, a scholar of the psychology of decision-making, suggests that the new data on the ways in which hyperchoice makes people less happy and worse decision-makers means that we “would be well served to rethink [our] worship of choice.”¹⁰¹ Indeed, in providing examples of how America is overly obsessed with choice, Schwartz highlights the bedrock principles of patient autonomy, writing, “medical ethicists treat the idea of ‘patient autonomy’ as sacrosanct, as if it goes without saying that having patients choose their treatments will make them better off.”¹⁰² Schwartz’s sentiment seems quite overstated, even if well-intentioned. Patient autonomy is important, not in the least because we have learned on several occasions how detrimental medical paternalism and lack of consent can be.¹⁰³ Moreover, even Schwartz admits that some choice is essential to human happiness and well-being.¹⁰⁴

Schwartz’s point, however, is well taken. Excessive choice may lead to lower quality decision-making—decision-making that is less informed and that makes use of information that is less well understood. The risks of hyperchoice are real and significant. Essentializing and the fatigue associated with sequential decision-making risk consent that is not informed. Arbitrary selection, opting out, and fear of regret in making the wrong morally relevant choice threaten to undermine potential tissue providers’ desire to provide tissue for meaningful research.

Still, tiered consent is likely to be the best way forward for obtaining appropriate consent from tissue providers. All available evidence demonstrates that having some choice is far preferable to having no choice (other than between participation and non-participation). Project-specific consent is likewise unattractive not only for its persisting administrative difficulties, but

¹⁰¹ Schwartz, *supra* note 88, at 74.

¹⁰² *Id.*

¹⁰³ The Nuremberg Code resulted from the post-World War II trials of doctors conducting unethical medical experiments on persons in concentration camps. The American experience includes the Tuskegee experiments, in which African American men infected with syphilis were monitored, but left untreated, in order to observe the disease progression. None of this research was done with informed participant consent. See Centers for Disease Control and Prevention, The Tuskegee Timeline (May 23, 2005), <http://www.cdc.gov/nchstp/od/tuskegee/time.htm>.

¹⁰⁴ SCHWARTZ, *supra* note 57, at 3.

also because it poses psychological burdens of its own. Thus, tiered consent, despite the potential pitfalls of information overload and hyperchoice, continues to represent the most promising methodology for serving the principles of disclosure, understanding, competency, voluntariness, and authorization that undergird informed consent while not overburdening either tissue providers or the research system.

Further empirical research on the psychology of decision-making and the scope of information load is needed, especially research focused on decisions made outside of the consumer context. In the first instance, it is unclear whether the ideal set sizes observed in consumer settings are applicable to informed consent. Various studies have shown that, with respect to consumer decision-making, sets sizes of six are preferable to those of thirty,¹⁰⁵ sets of six are preferable to those of twenty-four,¹⁰⁶ and sets of three or six are preferable to sets of nine.¹⁰⁷ Meanwhile, research also shows that sets of both six and thirty are preferable to no-choice conditions.¹⁰⁸ These results certainly support the conclusion that tiered consent is preferable to blanket consent; some choice is preferable to virtually none. Yet, do these results also indicate that tiered consent menus should include fewer than nine options? Intuitively, a list of roughly ten options seems likely to be a reasonable approximation of what the human mind can handle. This intuition lends additional support to my previous recommendation of a tiered consent of eight options for providing eggs for third-party use in Canada.¹⁰⁹ Still, this conclusion is simply an intuition, and its persuasive force is far from obvious, especially given the considerable complexity of the options in a tiered consent menu. Only with greater empirical

¹⁰⁵ Iyengar & Lepper, *supra* note 58, at 999.

¹⁰⁶ *Id.* at 997-98.

¹⁰⁷ *Id.* at 996 (discussing Danielle Timmermans, *The Impact of Task Complexity on Information Use in Multi-Attribute Decision Making*, 6 J. OF BEHAVIORAL DECISION MAKING 95 (1993) (finding that decision-makers used an elimination strategy twenty-one percent of the time when presented with three options, thirty-one percent of the time when presented with six options, and seventy-seven percent of the time when presented with nine options)).

¹⁰⁸ *Id.* at 1002-03.

¹⁰⁹ Ram, *supra* note 4, at 24.

findings can tiered consent models be appropriately designed to support and facilitate the choice and autonomy of tissue providers through free and informed decision-making, while not overburdening potential tissue providers through information overload likely to lead individuals to opt out of decision-making.

The importance of this research should not be underestimated. Numerous legal and ethics experts have already called for comprehensive changes in or wholesale replacement of national regulations and legal standards governing the provision of human tissue for research.¹¹⁰ Expert bodies and ongoing research industries have advocated, and in some instances already adopted, tiered consent as a best practice.¹¹¹ As legislators, agencies, and courts, working with ethicists and researchers, turn to implementing the best practice of tiered consent, they must be cognizant that, in an effort to give tissue providers choice, they do not instead end up undermining the essence of informed consent.

¹¹⁰ See, e.g., Ashburn, Wilson & Eisenstein, *supra* note 18, at 3378 (observing that “the current system for protecting tissue donors, which has worked in well in the past, is becoming and will continue to become increasingly obsolete”); Henry T. Greely, *Breaking the Stalemate: A Prospective Regulatory Framework for Unforeseen Research Uses of Human Tissue Samples and Health Information*, 34 WAKE FOREST L. REV. 737 (1999) (criticizing the National Bioethics Advisory Commission’s 1999 report for confining itself to the structures of the Common Rule, and offering an alternative proposal that departs from the Common Rule’s framework); Robert F. Weir, *The Ongoing Debate About Stored Tissue Samples, Research, and Informed Consent*, in 2 RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE: COMMISSIONED PAPERS, at F-1, F-18 (recommending an update to the Common Rule’s provisions regarding informed consent and waiver of informed consent).

¹¹¹ See, e.g., EISEMAN ET AL., *supra* note 4, at 134 (advocating tiered consent as a best practice); NAT’L BIOETHICS ADVISORY COMM’N, *supra* note 1, at 64-65 (same); Ram, *supra* note 4 (same); *What Is Tiered Consent?* (Dec. 27, 2005), <http://www.usm.maine.edu/bioethics/biobank/ethical/ic/tiered.html> (listing the options in the model consent form of the Tissue Access Working Group for consent to providing tissue to National Cancer Institute databases).