Developing Psychologically Compelling Understanding of the Involvement of Humans in Research

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Abstract

Research conducted on humans has a long history of ethical protections, with the Nuremberg trials in 1945 and 1946 triggering stronger protection across most jurisdictions. While there have been many reorientations and corrections in the emphasis of codes protecting human research participants, all have implicitly assumed a conception of human decision-making and the person that are psychologically not feasible. In this paper, we examine two problematic assumptions dominant in many research ethics guidelines: (1) implicit reliance on a model of classical rationality in conceptualizing the process whereby individuals make a decision of whether to give consent to participate in a study and (2) the assumption of autonomous subjects in the bioethical principle of autonomy and in operationalizing informed consent processes. For both of these problems, we outline theoretical psychological work that provides more compelling accounts of (1) human decision-making and rationality as bounded and ecological and (2) of personhood and agency as relational and emergent. We conclude by considering approaches to bioethics that are compatible with such conceptions of personhood and therefore provide a more satisfactory framework for a relational ethics.

Keywords Bounded rationality · Ecological rationality · Heuristics · Informed consent · Relational ethics · Research ethics

Introduction

Research involving human beings requires ethics oversight in most jurisdictions of research-intensive countries. There is good reason for this. People have been treated in horrible and inexcusable ways in the name of research. The purpose of research ethics oversight is to prevent such abuses from occurring, as well as to ensure the respectful engagement of human participants in research. In designing and implementing research ethics oversight both across

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and within particular jurisdictions, there are several challenges. One is to develop commonly agreed upon ethical norms that should guide research involving humans. Another is to apply these general principles in particular instances to make decisions about the acceptability of conducting particular studies. A key principle in most research ethics policies is that researchers must respect the autonomy of potential research participants, typically by informing them about the nature of the study, outlining all potential harms and benefits, and obtaining their informed consent before recruiting them into the study.¹ The emphasis in guidelines about these processes tends to be on the obligations of the researchers: they need to prepare adequate information materials and consent processes such that research participants are able to give their informed consent to be recruited into a study. What is often overlooked is that in the process of requiring researchers to respect participant autonomy through informed consent procedures, there are implicit notions of rationality, decision-making, and personhood that are imposed on individuals asked to make the decision about whether they will be part of a study. In this article, we argue that both the principles underlying research ethics oversight and the procedures that are commonly followed by researchers in involving human subjects in their studies rely on flawed models of decision-making and personhood. While we are strongly supportive of research ethics oversight in principle, we demonstrate that current ethical norms applied in such oversight rely on understandings of human beings that are not psychologically feasible. We draw on relevant research in theoretical, cognitive, and social psychology to demonstrate that more empirically grounded and theoretically sound models of personhood and decision-making are available that can constitute a stronger and also more ethical foundation for research ethics oversight. We begin by providing a brief history of the development of research ethics oversight, with a particular emphasis on the reliance on informed consent. We then discuss two specific problems: (1) implicit reliance on a model of classical rationality in conceptualizing the process whereby individuals make a decision of whether to give consent to participate in a study and (2) the assumption of autonomous subjects in the bioethical principle of autonomy and in operationalizing informed consent processes. For both of these problems, we outline theoretical psychological work that provides more compelling accounts of (1) human decision-making and rationality as bounded and ecological and (2) personhood and agency as relational and emergent. We conclude by considering approaches to bioethics that are compatible with such conceptions of personhood and therefore provide a more satisfactory framework for a relational ethics.

A Brief Historical Overview of the Development of Research Ethics Oversight and Informed Consent

The notion of informed consent has been shaped by a historical context in which avoiding the oppression of individuals by strong state power was blended with an ideology of isolated individuals as the agents of their own health and destiny.² In research ethics, informed consent was to provide the knowledge necessary for individuals to act as rational agents with the authority to decide what

¹ There are some notable exceptions, such as (1) studies that involve deception and in which participants are usually only told about their involvement in a study after data about them has been collected and (2) longitudinal cohorts or biobanks in which different models of consent may operate such that research participants may not have precise knowledge of every single study for which their data is used.

² There is good evidence that medical ethics and informed consent have a pre-Nuremberg history (Vollman and Winau 1996).

risks are acceptable and what benefits are sufficiently significant. The ethical justification for informed consent rested on the principle of respect for autonomy, or the idea that it should be the right of agents to decide, based on their own assessment, whether the benefits of research justify their acceptance of any risks associated with their participation in research.

The history and theory of informed consent have been extensively documented and analyzed (cf., Faden and Beauchamp 1995; Jonsen 2003). It is important to establish that the development of informed consent and respect for individual autonomy was an important step in the protection of research participants. It was to be a strong counter to the use of human subjects as mere means to an end—often understood as research intended to help others with little or no attention to the effects on the individual. While the Nuremberg War Tribunals in the mid-1940s presented horrific accounts of physicians', researchers', and medical administrators' abuse of persons in research, abuses were also identified in other countries, including the USA and Canada (Beecher 2001; Roland 2012).³ Importantly, many of these examples were not simply a failure to inform and receive voluntary authorization to involve subjects in research. The subjects were marginalized in their respective social and historical contexts and were effectively treated as disposable in comparison with the research objectives. The ethical principles developed to guide research were articulated in codes of ethics and in governmental reports, of which the US Belmont Report was probably the most influential (US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979).

The ethical principles used by most regulations and guidelines to govern research involving humans are practical guides that have been described as “being compatible with deontological and consequentialist and even with some aspects of virtue theory” (Pellegrino 1993, p. 1160). The principles of respect for autonomy, beneficence, and justice were authoritatively mandated by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), called *The Belmont Report*. The most popular and articulate defense of these principles (which divided beneficence into two principles—beneficence and non-maleficence) is found in the successive editions of Beauchamp and Childress's (2013) *Principles of Biomedical Ethics*, first published in 1979.⁴ The most thorough account of informed consent is probably R. R. Faden and T. L. Beauchamp's *A History and Theory of Informed Consent* (Faden and Beauchamp 1995), in which they briefly explain that “Nowhere in this volume do we discuss virtues or virtue theory because this is not the orientation we bring to the analysis of informed consent.” (p. 6). The seventh edition of *Principles of Biomedical Ethics* provides an account of moral character and virtue that supports a role for virtue as part of the “common morality” that the authors utilize in their account of the guiding principles of biomedical ethics (2013, pp. 30–61). Early legal cases treated informed consent as required to avoid charges of battery in clinical care (e.g., *Schloendorff v. Society of New York Hospitals*, 1914). More recently, N. Manson and O. O'Neill have argued that informed consent is better conceptualized as a waiver of normal rights, protections and prohibitions that fails in the absence of specific communicative conditions (2007), although the model of informed consent based on the principle of respect for autonomy continues to dominate ethical and legal discussions.

³ Prior to Nuremberg, various codes of ethics tended to lean on the virtue of physicians, which supported reflection on relationships (Osler 1907).

⁴ Another historically important formulation of applying mid-level principles to ethical dilemmas in health care is Jonsen et al. (2015).

Informed consent in research developed as a doctrine that promoted autonomous decision-making as a way to balance subjects' right to self-determination with the goals of research to benefit a wider population. The severity and currency of the recent discoveries of abuse probably helped speed the movement of these ethical discussions into law. The orientation of law to documentation and building evidence of informed consent as a defense of individuals and institutions no doubt played a role in the emphasis on documentation in the development of informed consent, as it does today. The development of committees to review research from an ethics perspective also required documentation of both the research and what would be told to the subject to support their decision.

Informed consent to research required that the research be distinguished from clinical care, in particular to avoid the mistaken presumption that research provided therapeutic benefits.⁵ The latter was generally understood to be activities intended solely for the benefit of the individual patient, whereas the goal of research was to produce generalizable knowledge that would be broadly beneficial. This might require that tests that are not needed for clinical purposes, standardization of interventions that would be different from clinical care, or even the provision of a placebo were clearly delineated from clinical care. Researchers were generally required to avoid making claims of benefit when an intervention was being assessed, usually because "clinical equipoise," or the genuine uncertainty about whether the intervention was effective, was the justification for additional tests, standardization and placebos (Freedman 1987; Miller and Brody 2003; Veatch 2007).

Problems in the Foundations of Research Ethics Oversight Relating to the Underlying Conception of the Person and Psychological Processes

Beyond Outdated Norms of Rationality: Ecological Rationality and Heuristic Decision-making

As outlined above, research ethics oversight generally requires that requests to an individual to take part in a research study be clearly delineated from activities relating to their care.⁶ The bright line between clinical care and research has historically been based on whether the purpose of the activities was focused solely on the patient's welfare, or whether it had another goal such as producing generalizable knowledge that might require the individual to be engaged in activities that would not have occurred in clinical care. Clinical care, then, has a fiduciary social and legal context that does not require patients to scrutinize or assess the trustworthiness of their care (Miller et al. 2018; Truog 2012, pp. 583–584). Accordingly, informed consent for aspects of clinical care is rarely explicitly documented unless the treatment is invasive, and often compliance to drug schedules or exercise regimes are under the control of the patient. In contrast, there is an expectation that when it comes to research, patients are encouraged to more actively assess the risks and benefits of their involvement in the study and, in particular, of any additional interventions they may be subjected to as a result of participating in research.

⁵ The therapeutic misconception is attributed to Paul Appelbaum and its introduction to bioethics to J. Kimmelman (Appelbaum et al. 1982; Kimmelman 2007). See also Beauchamp and Childress (Beauchamp and Childress 2013, pp. 133–134); Horng and Grady (2003).

⁶ For criticisms and debate about the ongoing validity of this demarcation, see Kass et al. 2013; Hallowell et al. 2009; Dobson et al. 2015.

Although research ethics committees assess research proposals to determine that there is a reasonable risk/benefit ratio to offer potential participants, there is a strong reliance on the informed consent process to act as a mechanism to ensure that individuals who agree to participate in a study are indeed satisfied with that decision. While there is an obligation for researchers to present information about the study to potential participants in an accessible manner, it is assumed that the participant will use that knowledge to make a “good” decision about whether to agree to participate. “Good” in this context, might be taken to mean that the participant weighs the risks and benefits of participating in the study in light of their personal values and preferences, and makes a decision accordingly.

Research ethics guidelines such as the TCPS2 have the following to say about the informed consent process in which individuals are asked to become research participants: “individuals who participate in research should do so voluntarily, understanding the purpose of the research, and its risks and potential benefits, as fully as reasonably possible.” (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada 2010, p. 27) While the guidelines have much of value to add about issues such as coercion, incentives, and the right to withdraw consent, they do not say much more about the decision-making process of individuals being asked to consent to research. However, the emphasis on what must be disclosed, and on the capacity to understand the disclosure, suggest that implicit in most informed consent processes is an emphasis on participants making decisions as rational actors who consider risks, benefits and alternatives before making a decision. The Canadian TCPS2, for example, lists 12 types of information and statements that constitute required information (Article 3.2). That is, it is broadly assumed that to reach a good decision, individuals will take into account all information provided to them, cognitively process the trade-offs between risks and benefits, and reach a decision that is optimal relative to their personal goals in the context of this decision. This model of human decision-making has been described as relying on standards of classical rationality (see below).

There is a vast literature on human decision-making that has accumulated over several decades. Early attempts to understand the ways in which human beings make decisions presumed that humans apply formal logic to real-world problems. Later models presumed that humans apply statistics to their observations of the real world to come to decisions. Both of these kinds of approaches are linked to ideas about rational reasoning with the implication that individuals who do not follow particular logical or statistical norms in their reasoning will reach decisions that are not “rational.” (Gigerenzer and Gaissmaier 2011).

A large body of empirical research on human decision-making has thus focused on analyzing deviations from “rational” decision-making. Particularly notable in this regard is the seminal work of Kahneman and Tversky. Their research program was premised on identifying systematic deviations from optimal decisions, which they attributed to the operation of biases and heuristics in human decision-making. Their research thus posited and relied on a distinction between normative ideals of rationality (the way optimal decisions *should* be made) with description of psychological reality (the way decisions *are* made). Heuristics, in the work of Kahneman and Tversky, thus denote the operation of “systematic biases that separate the beliefs that people have and the choices they make from the optimal beliefs and choices assumed in rational-agent models” (Kahneman 2003, p. 1449).

A dramatically different conception of heuristics in human decision-making has been proposed by Gigerenzer and colleagues. Drawing on the work of Herbert Simon, Gigerenzer (2000) distinguished between the norms of classical rationality and bounded rationality. *Classical rationality* here refers to the notion that for decisions to be assessed as rational,

there is a requirement that decision-makers have at their disposal and take into account all information about possible alternative outcomes, as well as their probabilities and consequences. These conditions generally do not occur outside of highly controlled conditions such as a psychology experiment. Real world settings require individuals to make decisions with limited information, limited time, and limited processing capacity (Gigerenzer 2000). A more reasonable requirement for considering decisions rational is therefore whether they are optimal given these constraints. Following Herbert, Gigerenzer terms this *bounded rationality*.

Whether a decision is good or not, therefore, needs to be evaluated not against unrealistic ideals of classical rationality (weighing all the conceivable options and their potential outcomes), but rather whether a decision satisfies thresholds of acceptability given the information and time that is available to make a particular decision in a particular environment. Heuristics, argues Gigerenzer, are therefore not sub-optimal and biased ways of coming to a decision, but rather highly adaptive cognitive processes that help us make good decisions.

Gigerenzer and Todd (2012) make the strong claim that the study of heuristic decision-making is not only a descriptive project; it is also a normative one. Gigerenzer and Todd use the term *ecological rationality* to indicate that criteria for successful decision-making must to some extent take into account success in the external world. In particular, judging the “rationality” of a decision process should not rely only (or at all) on the internal consistency of logical or statistical rules followed by the decision-maker, but rather on how well the decision-making process is suited to the particular environment in which the decision is made. A key aspect of understanding decision-making from an ecological rationality perspective is therefore to examine which heuristic tools are more or less effective in different situations and settings. Indeed, many studies now show that when heuristics are matched to the right environment, they lead people to make better decisions than if they had followed theoretically optimal decision rules (Gigerenzer 2008).

In short, there is strong evidence and wide-spread agreement among psychologists that human decision-making does not conform to standards of classical rationality (Gigerenzer 2000; Kahneman 2003). That is, on a descriptive level, humans generally do not make decisions in the way that is presumed to take place when individuals provide consent to take part in a research study. One might argue that on a normative level, potential research participants should make decisions in such a classically rational way, weighing all the benefits and risks of research participation, and making a decision that is an optimal reflection of their preferences and values. Drawing on the Kahneman and Tversky tradition of the heuristics and biases literature, one might presume that if informed consent were sought under the right conditions, individuals could be led to engage more deeply in the decision about whether to take part in a study, and thereby avoid a heuristic path to the decision. However, from a research ethics perspective, this would be odd, to say the least, because it would shift the normative burden to do consent “the right way” away from the researcher and to the research participant. It would imply that an individual’s consent could only be accepted if one could demonstrate that the decision was made “correctly” (weighing all potential risks and benefits), and not via the operation of a heuristic. Gigerenzer and colleagues’ treatment of heuristics leaves us with a much more intuitively compelling and indeed ethically palatable way out of this conundrum. If cognitive heuristics are an adaptive and effective way of making decisions in many aspects of our lives, then why not accept not only that this is how we make decisions about research participation on a descriptive level, but also *that we can use these heuristics to make good decisions about research participation*. In other words, Gigerenzer’s work on heuristics suggests that on a normative level, decisions about research participation may be

considered to be good decisions, even if an individual did not carefully weigh all the possible benefits and burdens.

A recent study on decisions to participate in research with young people with cystic fibrosis (CF) and their parents provides some initial evidence to illustrate our point (Christofides et al. 2016). CF is a chronic condition most often diagnosed in early childhood. Scientific advances in the treatment of CF have seen dramatic improvements over the last two decades, with life expectancy of individuals with CF now well into adulthood. While research has clearly benefitted individuals with CF, they have also contributed to this research as research participants. CF is a condition that comes with a significant burden of treatments at home and in clinics. Adding research participation to this already heavy load is not trivial. Individuals with CF are thus well positioned to appreciate both the benefits and the burdens of research participation. In an interview study with youth with CF and their parents, Christofides et al. (2016) found that, in general, they did not make decisions about consenting to participate in a study by carefully weighing all available information about the risks and benefits of the study to them. Many of the participants did consider these factors, but it was as part of a heuristic pathway. In particular, most participants started with a baseline tendency to “say yes” or to “say no” to requests to participate in research. This baseline response was described as being motivated by such reasons and factors as parents’ approach and attitude toward research, growing up participating in research (and so seeing it as part of their identity or part of the experience of illness), enjoying the process of research participation, trusting the researchers, and seeing the participation in research as an opportunity to help (the researchers, other patients, or themselves). The baseline response was then modified according to a number of cues that varied across individuals. Some examples of cues that affected decisions include whether the particular research topic was of interest to them, whether they had any concerns relating to the particular procedures involved in the study (e.g., some participants would avoid studies if they involved additional blood being drawn), logistical challenges (e.g., the study required an additional trip to the clinic), and particular risks associated with a study that might be seen as particularly salient given a patient’s specific medical condition. Figure 1 illustrates an example of a heuristic pathway of a fictitious patient beginning with a baseline of typically saying “yes” to requests to participate in research, and ending up saying no.

It is important to recognize that the situations in which individuals are asked to participate in research vary dramatically (Broome et al. 2001). Children with CF and their families are in a very unique situation, and so their experiences should not be generalized to all research contexts. Therefore, our argument here is not that the specific way in which the decision was made by the participants in this study is typical; rather, this study serves to illustrate the practical operation of heuristics in making decisions about research participation on a descriptive level (see also Reynolds and Nelson (2007), for another study illustrating heuristic decision-making in the context of requests to participate in research).

Beyond Isolated Subjects: Relational Understandings of Persons and Autonomy

Christofides et al. (2016) thus illustrate a general decision-making process that is at odds with implicit assumptions in research ethics oversight on descriptive levels (i.e., how decisions are actually made by potential research participants is not in line with implicit expectations in the research ethics community). We now argue that these insights also have important implications on a normative level (how decisions should be made) relating to implicit notions of the person.

Fig. 1 An example of the decision-making process for a fictitious participant, starting with a baseline inclination to participate that results in a final decision of "no"

Christofides et al.'s study illustrates the importance of particular types of considerations that are salient to individuals making the decision, which are not well characterized as either risks or benefits of participating. In particular, considerations that were often important included:

- A generally favorable perspective toward research of the parents of the individual making the decision
- Trust in the researchers
- Wanting to help

These types of considerations are not unique to this particular sample of participants. The importance of "wanting to help" was also observed in an adult sample of participants with CF (Christofides et al. 2017). Other studies have also shown that trust plays an important role in decisions about research participation, specifically trust in the researcher, the institution, and the consent process (Dixon-Woods et al. 2006; Woodgate and Edwards 2010). And, in general, studies have reported that many individuals who agree to participate in research report doing so for altruistic reasons (Broome et al. 2001; Ursin and Steinsbekk 2012).

Most research ethics guidelines would likely support the idea of individuals accepting advice from family and trusted friends and professionals when making decisions about whether to consent to participate in research. However, the emphasis in current research ethics frameworks would be on the autonomy of the individual and the decision being made after careful consideration of objective presentation of risks and benefits. Decisions based on trust of researchers, clinicians, or even parents would arguably be considered with suspicion according to informed consent guidelines that expect autonomous decisions based on consideration of all relevant information.

Most research ethics guidelines, such as the TCPS2, place a strong emphasis on recognition of the autonomy of the human subject. This is not surprising given that one of the four mid-level principles of bioethics is, indeed, *autonomy* (Beauchamp and Childress 2013). And there is good reason for this. Insisting on respect for autonomy in research ensures that researchers

do not act on other human beings or use their personal data in ways to which they object. This makes sense, in particular, when we think of Nazi doctors experimenting on their subjects or researchers in the Tuskegee Syphilis Study keeping life-saving treatments from their research subjects in the interest of maintaining the integrity of the study (Reverby 2009). However, when we consider many less dramatic instances in which researchers seek to involve persons in research, understanding the decision to consent to a research study as the decision of an autonomous agent, a “bounded being” independent of other “bounded beings” (Gergen 2009), becomes more difficult to sustain.

Martin and Sugarman (2003) observe that in recent decades there have been tens of thousands of research articles dealing with the “self.” However, the vast majority of these are empirical articles that use “operational indicators of self-concept, self-esteem, self-regulation, and self-efficacy” (p. 74) without evidence of clear conceptual treatment of what the “self” is or might be. Indeed, Martin and Sugarman criticize mainstream disciplinary psychology for having, on the whole, failed to engage with ontological questions as to the nature of the self, persons, and agency. This is not to say, however, that mainstream disciplinary psychology has not relied on an implicit ontological reading of personhood. Most of psychology, and, we suggest, most research ethics, has relied and continues to rely on an ontologically prior conception of personhood or what has been referred to as the presumption of persons as bounded beings (Gergen 2009). Beyond psychology, the particular concept of personhood that has been dominant in Western ethical and political theory posits an entity that is “independent, rational, self-aware, self-reliant, self-interested” and “engaged in the autonomous pursuit of his interests” (Baylis 2012, p. 112). In short, we suggest that most of psychology and research ethics relies on atomistic conceptions of the person. Although we interact with each other in various ways, our identity, our sense of self, our consciousness, is generally viewed as contained and clearly distinguished from that of others.

Such atomistic accounts of persons have been criticized for centuries and scholarly works in several disciplines, including philosophy, sociology, anthropology, and nursing, have advanced relational accounts of identity, agency, and personhood. Slife (2004) observes differences between weak and strong relational perspectives of persons. Weak relational perspectives simply acknowledge that external influences operate on individuals, and then become internalized. Slife argues that this conception of relationality is well recognized and already incorporated in most of disciplinary psychology. Relationships, in this view, are then simply interaction between entities that are each self-contained, though of course these entities (persons) are in part conditioned by past and present features of their environment. As such, weak relational views constitute and further reinforce atomistic or individualistic conceptions of the person. Strong relational perspectives, in contrast, view persons as inherently relational. That is, rather than viewing relationships as constituted by distinct entities, *persons are viewed as constituted by relationships*. Here, the person is not viewed as ontologically prior, but as emergent from the relational context in which we exist. This is not to say that our consciousness, our sense of self and agency are epiphenomenal. Rather, it is that the manifestation of these phenomena follows from the relational contexts of life and does not precede them.

A full review of relational accounts of being is far beyond the scope of this article, as is their philosophical heritage. Suffice it to say that there are many. Nevertheless, as Gergen (2009) notes, there is a strong “culture of bounded being” (p. 20) that permeates at least Western societies. And this is certainly not helped by the relatively recent rise to dominance of neoliberal notions of subjecthood, with their emphasis on the centrality of the self and the utilitarian, calculating mode of

thinking that is presumed to be the normative ideal of successful persons (Teo 2018). In contrast, relational accounts of persons posit that our actions, decisions, goals, and purposes cannot be understood only according to some theoretical abstractions of what motivates people. Rather, actions, decisions, goals, and purposes only gain meaning in the context of how we relate to those around us; they can be understood only through the meaning they acquire by virtue of existing in relationships. For example, hitting a ball over and over again with a bat and going to great lengths and expense to watch others do the same make sense only in the context of the relationships that have over time, historically and in an individual's life, culminated in and circulated around the game of baseball. Being nervous about purchasing a ring of shiny metal that can be placed around a human finger makes sense only in light of my relationship to another person to whom I wish to give it, and all the relationships historically that give meaning to this act and the antecedents and consequences associated with it. As Rutherford (2018, p. 628) explains, "choices are always made in context, and that choice itself only makes sense when context is taken into consideration. This context includes the subject positions of the "choosers" and the larger systems in which they are embedded."

In their development of a conception of (psychological) personhood, Martin and Sugarman (2003) observe tensions between atomistic notions of persons and sociocultural (relational) accounts. The latter, rather than presuming persons to be ontologically prior, generally view persons to be emergent from the particular social context into which they are born. These views thus see the self as a product of contingent forces, rather than having an existence separate from or independent of social and cultural contexts. However, the problem with some sociocultural accounts is that while they strongly resist neurological or other biologically determinist notions, they often tend toward eliminating recognition of individual personhood and agency through reducing these to social and cultural determinants. Martin and Sugarman (2003), therefore, suggest a conception of the person that takes into account the sociocultural embeddedness, and as such the fundamental relationality, of being, while also recognizing that agency (in an ontological sense) can be seen as emerging from these conditions. In particular:

Our conception of a person (or psychological person) is an identifiable, embodied individual human with being, self, and agentic capability. The adjective identifiable references the physical characteristics and social identity of a person. Social identity refers to those socially constructed and socially meaningful categories that are appropriated and internalized by individuals as descriptive of themselves and/or various groups to which they belong (e.g., female, African American, soccer player, attorney, mother, community leader, and so forth). The adjective embodied captures the sense of a physical, biological body in constant contact with the physical and socio-cultural life-world. Being refers to the existence in such a life-world of a single human being (an individual). Importantly, the manner of such being is historically and socioculturally effected within traditions of living. Self, for us, is not a substantive entity but a particular kind of understanding that discloses and extends a person's being and activity in the world. It is that compelling comprehension of one's unique existence that imbues individual experience and action in the world with significance and provides a phenomenal sense of being present. (Martin and Sugarman 2003, p. 78)

In this context, Martin and Sugarman view agency as the activity of a person in the world.

In contrast to biological determinist and some sociocultural accounts of persons, they thus see a place for true deliberative agency. However, this deliberative agency is not prior to our emergence in the world; it is rather an agency that is associated with the development of the

person within particular material, sociocultural, and relational contexts. This deliberative agency, therefore, is not the property of an ontologically prior being; it is the property of a person whose identity, purposes, goals, and aspirations are all deeply embedded and emergent from the relationships that contribute to their formation.

Adopting such a perspective of personhood and agency allows for novel way of viewing the act of consenting to a research study. In particular, it suggests that the decision to say yes or no to an invitation to participate in research cannot be understood simply through a calculation of risk and benefits. Rather, the relational and psychological context within which the decision is made needs to be considered:

- What aspirations does the act of research participation serve?

e.g., owing to my disability I am not able to contribute to society via regular employment; participating in research allows me to contribute meaningfully in spite of my other limitations

- How does the act of participation serve or hinder some relationships?

e.g., it allows me opportunities to interact with my doctors or other patients/participants in new ways and build my relationships with them in new contexts;

e.g., it places additional burdens on my family, as someone will have to take time out of their work day to drive me to the study site

- How does research participation in particular studies relate to particular institutional arrangements?

e.g., the research will be used by private sector companies and not available in the public domain

e.g., the research will strengthen the position of particular groups or organizations with whom I identify

While there are many ways in which relational considerations can have important bearing on the decision to participate in research, we want to emphasize, in particular, considerations relating to trust. Arguably, many of our actions and decisions on a daily basis rely on trust. It is simply not possible to analyze the risks and benefit of every single decision we face. We trust that drivers of automobiles will follow the rules of the road when we cross the road; we trust that the chef in the restaurant followed proper food safety procedures when preparing our meal; we trust our parents to act in our best interest. Trust is thus an important heuristic cue in navigating our social and material world. Of course, there are instances in which someone may not have trust in the examples listed above. An individual may not trust a particular restaurant to prepare food in a safe way and another individual may not trust their parents to act in their best interest. In these cases, there are likely reasons why the relationship is not characterized by trust. And it is in these instances that we may need to scrutinize both the particular decision and the relationship in more depth. The question then is whether the decision to participate in a particular research study is such an instance.

Moving Beyond Autonomous Subjects and Outdated Norms of Rationality

The Role of Relational Ethics

There has been considerable critique and alternative approaches to the standard principlism that dominates bioethics. There have been critiques from feminism, social sciences, and cultural studies (cf., Fox and Swazey 2008; Hoffmaster 2001; Sherwin 1992; Stephenson 1999; Weish 1990). Contextualism, ethics of care, narrative or naturalized bioethics, and an emphasis on relationships and empathy have sometimes supported independent theories intended to replace the principlism and its inherent dependence on Western liberal assumptions (Gilligan 1982, 1982; Held 2006; Lindemann et al. 2009; Noddings 2003; Slote 2007; Winkler 1996). Many attempts to understand relational ethics in the context of the dominance of principlism treats competing ethical theories as complementary—together they provide insights that collectively provide a more complete account of particular ethical issues or problems (cf., Rodney et al. 2013). Central to theories of ethics based on care, relations, or empathy is that an adequate account of ethics must include sentiments or feelings, and consider them in the context of particular relationships. Often contexts with asymmetry of power are key considerations, as are the capacities of persons to care. We will not attempt to establish the theoretical superiority of any single ethical theory. Rather, we will argue that as theoretical approaches they provide support for understanding moral agency, choice, and informed consent in terms of heuristic decision-making and a relational, situated understanding of the person. Such approaches include consideration of the magnitude and probability of benefits and harms, but also the relations of trust and power that are inevitably part of research participation and clinical care. But these considerations are not simple and may lead to surprising conclusions.

Many features of an ethics of care are important to understand the epistemological, ethical, and political goals of supporting choice and agency as reflected in practices of informed consent. In contrast to the dominant focus on informed consent and autonomy, an ethic of care locates ethical decisions in a context of relationships and can bring into play notions of narrative ethics. In addition to the understanding of relevant information and absence of coercion or manipulation, choice contexts must also reflect on whether they support, or at least do not undermine, empathetic relations between participants and researchers, as well as between participants and other persons important to them.

Most relational ethics theorists contrast their approach to liberal theories of ethics such as Bentham, Kant, Mill, and Rawls on the grounds that such liberal theories tend to conceive of the individual as atomistic.⁷ Personal identity is constituted by essential characteristics that individuals have across all possible situations. On this liberal account, the support of the exercise of self-aware critical scrutiny provided by informed consent is the hallmark of true freedom as it allows the expression of one's autonomy and identity. Alternatively, relational ethics views the individual as in an important sense relational, and identity as tied up with relations with others. Philosopher Michael Slote (2007, pp. 76–82), paraphrasing Bernard

⁷ The term “liberal” is usually used to locate the ethical theories in the context of Western, liberal democracies and their political assumptions. We will use this convention, but do not mean to imply that care, empathy, naturalistic, or narrative ethics escape these assumptions, nor that they are necessarily wrong, although they may be inadequate as described in this paper. Similarly, we will use “relational ethics” to refer to theoretical perspectives that develop a notion of agency that is constitutively grounded in relationships, embodiment, caring, and empathy.

Williams (1981), provides the example of a man who saves his wife over a stranger only after having consulted morality and deciding that it is morally permissible to save his wife. The relationship, the husband's love for his wife, ought to be an adequate guide and motivator of action. Making relationships an object of critical scrutiny is often intended to protect marginalized or disempowered people, as in the example of the exploitation of women under patriarchy. Slote asks "But does it seem odd or ridiculous, doesn't fit, for a woman to be questioning, say, her love for her parents without having a particular reason to be suspicious of that love?". Slote suggests that the emphasis on critical *vigilance*, or the subjection of all relationships to examination, needs to be distinguished from critical *responsiveness*, which allows the fuller sense of caring, connectedness, and love, to be valued, while maintaining that when there is reason to become critical, then critical responsiveness is appropriate. While relational ethics respects autonomy and the exercise of critical self-reflection, it also values caring relationships and does not advocate that all such relations and the actions they engender need to be critically scrutinized, although some do.

Relational Ethics and Choice

This discussion maps onto discussions of informed consent as "choice" in interesting ways. The distinction between research and clinical practice suggests that clinical practice is based on a fiduciary relationship in which the physician acts solely in the patient's interest, whereas research introduces additional motives. Research therefore requires informed consent, and historically this led to requirements of ethical review as well. The implication might be that in clinical care, there is no reason to engage responsive scrutiny. Even if the patient does not fully understand and commit to a course of treatment, the fiduciary nature of the relationship protects the patient and may be more important than the exercise of autonomy through scrutiny (the legal distinction between valid consent and standard of practice supports the independence of these assessments). In contrast, historical examples of research failing to show adequate respect for the individual participants are numerous, whether war crimes where people were not treated as persons, natural history research that denied established treatment (e.g., Tuskegee Syphilis Study (Reverby 2009)), or the use of samples from patients without their consent (e.g., Moore (Moore v. Regents of University of California 1990); the case of Henrietta Lacks (Skloot 2010); the case of the Havasupai (Garrison 2013)). Perhaps the most influential aspect of research that stimulates distrust and responsive scrutiny is the involvement of private enterprise with its emphasis on profit. Informed consent seems far more important in the context of research to be sure that an extension of the belief in caring relations, or trust in professions and institutions, does not lead people to participate in research where they have reason to scrutinize the activities and their involvement. Here, the involvement of health professionals who might stimulate trust and belief in caring relations is in a context of complicated motives that require scrutiny in response.

Relational ethics supports the need to provide information that might call for closer scrutiny of the relationship and choices associated with research participation, but information and voluntariness are not sufficient. It is also important for research participants to be able to consider whether they can trust researchers, or better the research team, to act in ways that are at least considerate and oriented toward their well-being when conducting the research. Further, while information about research describes how the participant will be involved, considerations of the effects of participation on the circle of people to whom the participant has responsibilities and concerns are also relevant. For example, reassurance that a procedure is safe or precautions adequate to manage risks may not

reduce resistance if it is based on concern about how participation will affect others. Parents might be concerned about schedules that conflict with other responsibilities. Further, determining personal interests may not be sufficient for good choices when a participant wants genetic information but is concerned about its effects on family members.⁸

Of course, there are numerous historical examples of clinical care where the presumption that the physician was acting in the patient's best interest fell under scrutiny and was found lacking. Decisions related to women's health were, and often still are, based on oppressive presumptions about women's nature, roles, and capacities. Marginalized and racialized populations have good reason to be suspicious that they may receive different treatment than others. These are examples of context where the presumption and dependence on trust and care are problematic. But liberal theorists writing on informed consent do not insist on "authentic" or self-aware scrutiny of the context and information for informed consent to be valid and treatment provided. In their important work, "A History and Theory of Informed Consent," Faden and Beauchamp (1995) argue that a "substantially informed and voluntary" consent is adequate, and that to insist on more of an emphasis on rational and independent choice might lead to harms as a result of not providing appropriate care.

Relational or care ethics does not need to insist on unrealistic notions of fully "authentic" informed consent to emphasize that there are situations where the presumption of trust and empathy needs to be scrutinized. Further, attention to participants' notions of self and responsibilities helps understand diverse choices, selective hearing of information, and assumptions of trust or distrust. The emphasis on information and voluntariness is important, but tends to become an ideal for choice, such that consent forms and processes often seem like an argument for participation that require justification to decline. Expanding the concept of choice as suggested by relational or care ethics supports a wider set of considerations. There is a complex interaction between the immediate relationship with the research team, the conditions of participation, the effects of participation on the individual and on others to whom they exercise care and empathy, and historical and social conditions that may stimulate trust or distrust, or justify responsive scrutiny. Support for choices based on this ideal will encourage participants to consider how participation in research may extend and restrict their exercise of care and empathy, including consideration of all persons that participants consider relevant.

Conclusion

The ideal that seems presupposed by contemporary approaches to research ethics and informed consent leads to several problems to which relational or care ethics provide responses. Recognizing that choices to participate in clinical care are dependent on a presumption of the fiduciary relation—the proposed options are only motivated by concern for patients' well-being—is often contrasted with the choice to participate in research. But the context of clinical care includes influences on health advice that are potentially in conflict with patients' welfare, including commercial influence, allocation decisions in the health system, and historical experiences that stimulate distrust. Empathy or care ethics suggests that in these circumstances, the presumptions of care and trust require responsive vigilance in which patients need to consider whether their assumptions are justified or need recalibration. This moves choices in

⁸ This has been characterized as "relational responsibility" and developed elsewhere in relation to genetic testing (cf., Burgess and d'Agincourt-Canning 2001; d'Agincourt-Canning 2001).

clinical care closer to the choices regarding research participation (which often benefits from the presumption that the fiduciary clinical relationship has been extended).

The model of the rational decision-maker suggests that choice requires a kind of authenticity, or awareness of how culture and social context shapes our values and the options we are given. But this is unrealistic for choices about research participation and clinical care. As a result, rational, free choice is diluted to the realistic goal of “substantially informed and voluntary consent.” Relational or care ethics proposes that appreciation of the relational aspects of choice—the trustworthiness of the context and consideration of the wider set of persons to whom the participant has responsibilities—modifies the characterization of the ideal of choice. The liberal ideal of rational choice might claim that there is ample room for diversity of values in the exercise of informed consent. Yet there is nothing in informed consent that stimulates participants to consider whether they need to be responsively vigilant due to contextual elements. Further, the information given in informed consent processes must provide an explanation of why risks and inconveniences are necessary and justified by the research, effectively providing a persuasive argument for participation. Implicit in this is an appeal to empathy and care beyond that of the participants. But participants must consider this possible act of care or empathy in comparison to the effects of participation on other obligations and opportunities for care and empathy. The ideal model of choice is substantially informed and voluntary participants who themselves consider how they want to be empathic and caring in the context of the opportunity to participate in research, and the effect that would have on other opportunities and responsibilities to be empathic or caring.

A more relational approach to informed consent to research needs to recognize that researchers and participants probably begin from presumptions about their role in actions that benefit others, including participation in research. Participants may consider elements of participation to be benefits, but ethics committees may resist allowing researchers to describe these elements as benefits for fear of manipulation and therapeutic misconception. The emphasis on disclosure that often leads to overwhelming amounts of information may sometimes undermine participants’ global understanding of the research. But as a performative action, disclosure seems to be part of the ritual of communication and trust building that a relational approach needs to affirm. Weakened disclosure may reasonably stimulate participants’ distrust.

Participants accede or choose to participate in research in the context of their own lives and identity. They may well see participation as making contributions or fulfilling perceived obligations. A relational approach would, at least in proportion to risk and inconvenience, explore participants’ expectations and whether participation aligns with them. Important family members, friends, or colleagues may support or challenge these expectations and participation, so providing time to talk to important persons prior to accepting a commitment to participate may also be important in some cases. Although trust is often assumed, it is reasonable to explain how a research project and the researchers merit trust. This could include describing ethical and scientific review and how conflicts of interest are managed. Participants may think of themselves as unique in their role as participant, or as part of a wider group. Providing an opportunity to discuss participation with other research participants may provide more of a sense that each participants’ contribution to research is part of a larger activity, and bring confidence to the act of participating. Finally, relational approaches to informed consent, in recognizing that the wider community shapes and is affected by research participation, suggest that wider community input into ethics review and research design may build processes that are better understood, are responsive to community expectations, and are more trustworthy.

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