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Person-Oriented Research Ethics: Integrating Relational and Everyday Ethics in Research

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Abstract:

Research ethics is often understood by researchers primarily through the regulatory framework reflected in the research ethics review process. This regulatory understanding does not encompass the range of ethical considerations in research, notably those associated with the relational and everyday aspects of human subject research. In order to support researchers in their effort to adopt a broader lens, this paper presents a "person-oriented research ethics" approach. Five practical guideposts of person-oriented research ethics are identified: (1) respect for holistic personhood; (2) acknowledgement of lived world; (3) individualization; (4) focus on researcher-participant relationships; and (5) empowerment in decision-making. These guideposts are defined and illustrated with respect to different aspects of the research process (e.g., research design; recruitment, data collection). The person-oriented research ethics approach provides a toolkit to individual researchers, research groups, and research institutions in both biomedical and social science research wishing to expand their commitment to ethics in research.

Keywords: Research Ethics; Human Subjects Ethics; Informed Consent; Justice in Research; Public Trust; Vulnerable Populations

Introduction

Researchers are often familiar with research ethics through official research ethics guidelines, regulatory requirements, and the regulatory-like reviews performed by research ethics committees (Schneider 2015; Trudel and Jean 2010; van den Hoonaard and Hamilton 2016). This limited understanding and appreciation of research ethics quickly becomes an operational framework, a paradigmatic reduction of research ethics to the domains of informed consent, privacy, and confidentiality through concrete measures such as informed consent forms and privacy-protection procedures (Brosnan et al. 2013; Friesen et al. 2017). This regulatory paradigm – and the stereotypical way of conceiving research ethics it is premised on – offers limited engagement with the core values and principles promoted by official research ethics guidelines (Department of Health and Human Services 2009, Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada 2014, United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1978). It also has the unfortunate drawback of considering human relationships between investigator and research participant through the lens of regulatory requirements (van den Hoonaard and Hamilton 2016). However, official research ethics guidelines and review are by no means the be-all and end-all of ethics in the practice of research (Anderson et al. 2011). Several scholars have proposed ethical approaches beyond or beside the regulatory paradigm (van den Hoonaard and Hamilton 2016). For example, Emanuel and Grady (2007) have described how — in spite of the dominance of the paradigms of "Regulatory protectionism," and to some extent "Participant access," which

focuses on the documentation of informed consent[1] — some studies have adopted a paradigm of "Community partnership" where subjects are considered to be active participants in the research enterprise. Related to this focus on active participation, in a recent analysis of the Belmont Report, Friesen and colleagues (2017) write, "The Belmont Report's emphasis on researchers' duty to protect participants is admirable and necessary. Yet this duty should be augmented by a duty to include individuals from excluded and vulnerable groups in the research process. Inclusion should be understood to mean including those who not only have been left out as participants but as research partners who can help shape the research goals and protocols." (Friesen et al., 2017, 19). Accordingly, there is a need for greater focus on how that participation and inclusion can occur most efficiently and effectively to promote societal good through valuable research. Our paper addresses this need by presenting a toolkit of practical guideposts and examples of successful "person-oriented" research that follow this path.

In order to support researchers in their effort to adopt a broader lens regarding research ethics (i.e., beyond the regulatory paradigm), this paper describes a "person-oriented research ethics" approach that can be applied to research in any field: social or biomedical sciences, participatory or top-down study designs, qualitative or quantitative designs. It draws on key features of the clinical concept of patient-centered care and how it can be applied to the research context based on synthesis and critical analysis of a diverse range of literatures of person-centeredness in research. Five practical guideposts of person-oriented research are identified, explained, applied to the research process and illustrated with specific examples from the literature. We hope that this model will be useful to researchers by providing a toolkit for

[1] Following an initial paradigm of "researcher paternalism."

research design and execution; to research ethics committee members to assist in evaluating designs; and to ethicists for synthesizing and bringing clarity to a range of literatures applying person centered concepts in a research ethics context. It can also be used as a framework for identifying or developing models of person-oriented research ethics for specific research topics, as we are currently doing for research involving participants on the autism spectrum (Cascio, Weiss, and Racine 2017). The person-oriented research ethics approach is by no means a replacement to standard and established research guidance but an effort to articulate some of its interpersonal and everyday aspects that tend to get lost when research ethics is reduced to a regulatory paradigm.

Common Understandings of Research Ethics (The Regulatory Paradigm)

Research ethics is a rich area of scholarship but, in practice, researchers continuously report an experience and an understanding of research ethics that equates it to a regulatory paradigm (Brosnan et al. 2013; Friesen et al. 2017). For example, in a study of UK neuroscience researchers, Brosnan et al. (2013) relate that "It soon became clear in both the observation and interviews that the *dominant* meaning of ethics in the group was the external regulatory approvals required to conduct research [….] nearly half of the interviewees confounded ethics and regulation" (emphasis added). On the other hand, bioethicists, patients, participants, and researchers have criticized the regulatory focus on protecting research subjects, particularly in the context of research regarding life threatening-illness where research ethics is sometimes considered to be an obstacle to research (Emanuel and Grady 2007, Deslauriers et al. 2010). As a result, some researchers distrust research ethics committees, accusing them of being more interested in protecting the institution than in protecting research participants (Whitney et al. 2008). This does not mean that some obstacles to research are not well justified. However, this

malaise and miasma of mistrust between researchers and research ethics committees may contribute to a narrow understanding of ethics – an understanding in which more relational and interpersonal aspects of research may not be addressed because research ethics becomes equated to regulation, bureaucratic procedures, and administrative requirements (Deslauriers et al. 2010, Van den Scott 2016). Indeed, Deslauriers et al. (2010) suggest that, in the field of neuroimaging research, researchers may rely too much on research ethics committees for guidance and do not see ethics as a shared responsibility that researchers also hold, thereby partly overriding or suppressing their own sense of ethics in favor of a regulatory process. This view of ethics is also transmitted to younger generations of researchers. Van den Scott writes that: "Research ethics boards socialize graduate students into thinking about ethical research in terms of the framework created by the ethics boards [….] As we know, filling out forms has little to do with ethics (Iphofen 2011), yet ethics review boards impress upon students that it constitutes ethical research" (van den Scott 2016, 233). Moreover, regulatory-based discussions of ethical conduct of research often focus on challenges and historic abuses rather than on opportunities and successes (Friesen et al. 2017, Mathews, Fins, and Racine 2018). Much current regulation has emerged from historical scandals of unethical research, including the medical experiments of the Nazi doctors during World War II, the Tuskegee syphilis study, and Willowbrook State School hepatitis study in the United States (Friesen et al. 2017, Rothman 1991).

Many scholars have now written on the limitations of research ethics review and the tensions between researchers and research ethics committees created by the experience of challenging aspects of the ethics review process (Schneider 2015; Trudel and Jean 2010; van den Hoonaard and Hamilton 2016). Difficult experiences have been reported with respect to obtaining multi-site approvals (Burris and Moss 2006; Deslauriers et al. 2010; Racine et al.

2010), undertaking international research (Burris and Moss 2006; Dawson and Kass 2005), proposing community-based participatory research (Tamariz et al. 2015, Shore et al. 2011), and fulfilling requirements for consent forms that are excessively complex, lengthy, or legalistic and counter to the goals of voluntary informed consent (Burris and Moss 2006; Dawson and Kass 2005; Whitney et al. 2008). By contrast, others have suggested that criticism of the research ethics review process is exaggerated (Guta et al. 2012) and some researchers report positive experiences (Shore et al. 2011). One of the important gaps in researchers' experience of research ethics as a regulatory paradigm is the silence of the regulatory paradigm on the relational aspects of human subject research (Lahman, Geist, et al. 2011). The relational and everyday aspects of research, such as how to communicate with subjects, how to respond to their questions and concerns, or how to design research that will build explicitly on participants' perspectives and ensure that subjects are treated fairly can represent a significant source of ethical tensions (Banks et al. 2013, Guillemin and Gillam 2004). These aspects of research practice may not have much to do with the more decisive issues of, for example, consent and procedures for the respect of privacy at the core of the regulatory paradigm. Another important gap, explainable by the way researchers experience research ethics as regulation and bureaucracy, is its limited aspirational pull (Schneider 2015; Trudel and Jean 2010; van den Hoonaard and Hamilton 2016). Research ethics most often refers to and is experienced as a set of obligations rather than ideals about what a good researcher could be or what an ethical interaction with a research participant might look like (Doucet 2002).

The fields of ethics and bioethics take a broader view of research ethics as more than mere regulation, as do some individual researchers and research teams. Bioethics scholars have proposed such concepts as relational ethics (Meloni, Vanthuyne, and Rousseau 2015) and

relational autonomy, evidence-based research ethics (Kalichman 2009), everyday ethics (Zizzo, Bell, and Racine 2016, Dresser 2015), reflexive research ethics (Cordner et al. 2012, Lahman, Geist, et al. 2011), and goodness-of-fit ethics (Fisher 2003b, a, Fisher 2002) to describe more comprehensive approaches for clinical and research ethics. Many of these approaches draw explicitly or implicitly on Carol Gilligan's ethics of care, understood as a complement to but not replacement of more legalistic and regulatory understandings of ethics (Benner, Tanner, and Chelsa 2009). Drawing on this literature, the person-oriented research ethics approach described in this paper does not replace current regulatory approaches or engage with regulation *per se*; rather, it complements the regulatory approach by proposing practical guideposts to guide the everyday and interpersonal aspects of research.

Person-Centered Care as a Precursor to Person-Oriented Research Ethics

The approach of person-oriented research ethics originates with the idea of applying concepts of person-centeredness (patient-centeredness, family-centeredness, etc.) developed in clinical ethics to supplement the understanding of research ethics under the reductionist guise of a regulatory paradigm. The concept of person-centeredness has a long history in a range of healthcare settings through the theory and practice of patient-centered or person-centered care as an antidote to depersonalized care (Chenoweth et al. 2009, Slater 2006). Patient-centered care, as defined by the US Institute of Medicine, refers to "providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions" (Institute of Medicine 2001). The concept of person-centeredness can be applied to not only clinical ethics, but potentially also to research ethics in order to capture some of the more interpersonal aspects of research ethics and promote respect for persons throughout the research process (Kost et al. 2013). Indeed, person-centered care has been

applied in research in a variety of ways, detailed below. Some of these are participatory, qualitative, and ethnographic methodologies more commonly (if stereotypically) associated with care and individual values. Others have applied person-centered principles in more traditionally positivist study designs such as clinical trials (Oviedo-Joekes et al. 2015) or person-oriented research in developmental psychology (Bergman and Andersson 2015). There are many parallels between person-centered care and the research process, which we will unpack shortly. A key difference, however, is that care is oriented by the individuals' needs, but research is oriented by research questions guiding a given study (Berg et al. 2001; Buchanan and Brock 1990). Therefore, the individualization component of person-centeredness (see below) poses perhaps the most direct challenge to the influence of these ideas in the research context, which often requires standardization rather than individualization with respect to the protocol. Nonetheless, while the entire protocol cannot be individualized, there are ways in which individualization is possible. For example, participants can be offered multiple means by or orders in which to complete a research task, and researchers can investigate statistically whether these means made a difference (Davis et al. 2005). This difference in the use of individualization between care and research is the main reason we have chosen to use the term person-oriented rather than person-centered, because ultimately the research question is central to a study.

It is important to note that some research designs (for example, participatory action research, community-based participatory research, or the PhotoVoice method) *do* involve or indeed require participant negotiation and choice, to the extent that they may even be called "participant-centered" (Lal, Jarus, and Suto 2012). It is precisely because person-centeredness (i.e., participant-centeredness) is more associated with participatory research and the social sciences that we here provide examples primarily from the clinical sciences, to illustrate our

point that this space exists not only in community-based participatory research which explicitly aims to be participant-led, but also in hospital-based researcher-led protocols. These guideposts are in line with national goals for patient-oriented research, for example in the United States (National Institutes of Health 2016, Department of Health and Human Services 2009) and Canada (Canadian Institutes of Health Research [CIHR] 2011). They also align with calls for advocacy groups and individuals to be treated as partners in the research process, and also with pragmatist approaches in research ethics (Brendel and Miller 2008; Racine 2010).

Developing a Concept of Person-Orientation in Research Ethics

To develop a person-oriented research ethics and identify related previous proposals, we searched both MedLine and the Social Sciences Citation Index for relevant bioethics literature using search terms such as: relational ethics, interactional ethics, reflexive ethics, reflexive research ethics, contextual bioethics, critical bioethics, goodness-of-fit ethics, supported consent, individualized communication and consent, relational autonomy, everyday ethics, evidence-based research ethics, patient-oriented research, participant-centered research, person-centered research, person-oriented research and related terms. We draw on these and related bodies of literature to propose a model of person-oriented research ethics, based on five core practical guideposts. Before introducing these guideposts, we here briefly summarize like-minded proposals offering important background for person-oriented research ethics. These precursors include everyday ethics, person-centeredness and participant-centered research, and patient-oriented research. We conclude this section by explaining briefly how person-oriented research ethics differs from these previous concepts and provides a broader approach applicable to research in any field.

Everyday Ethics

Person-oriented research ethics draws heavily on the concept of "everyday ethics" (Zizzo, Bell, and Racine 2016) in that it attends to more quotidian and interpersonal aspects of care. These aspects can nevertheless involve important and value-laden decisions. Building on this literature, person-oriented research ethics can serve a similar role of bringing the everyday ethics of research to the forefront. Although research ethics tends to encapsulate the requirements of common research ethics guidance, translating person-centeredness into person-oriented research focuses instead on the everyday ethics of the research process.

Person-Centeredness and Participant-Centered Research

Several scholars have written on the use of person-centeredness or adjacent concepts (e.g., patient-centeredness, family-centeredness) in research ethics, which also inform our approach. Perhaps the most direct application of person-centered care to the research process comes in the literature on participant-centered research (Kost et al. 2013), which can be defined as "research that addresses participant needs, interests, and abilities as well as accepted standards of scientific rigor" (Gross and Fogg 2001). Participant-centered research attempts to place participants' interests, values, and experiences at the center of the research design to create better, more meaningful, scientific knowledge and support the inclusion of a range of potential participants and participant populations. These concepts are contrasted with other forms of centering such as "protocol centered" (Davis et al. 2005), "variable-oriented"/"variable-centered" research (Bergman and Andersson 2015, Meyer and Morin 2016), or "laboratory-based" outcomes (Winstein et al. 2003). It should be noted that these terms are often used to describe specific types of research, couched within particular disciplines or methodologies. For example, the term "participant-centered research" is often, although not exclusively, used in

descriptions of certain methodologies such as participatory research (Azzarito 2016), participatory action research (Collie et al. 2010, Lal, Jarus, and Suto 2012), and action research (Weaven and Clark 2013). Researchers also describe participant-driven research as "participant-centered" or "person-centered." Examples of such research include PhotoVoice or other media-elicitation types of studies (Lal, Jarus, and Suto 2012) or person-centered interviewing (Simon 2012). The terms "person-oriented" and "person-centered" have also been used in developmental psychology to describe an approach to theory and methods (especially for data analysis) that contrasts with the "variable-oriented approach" by considering human development as individual-specific and the individual as a complex, holistic, and organized whole (Bergman and Andersson 2015). Similarly, the term "person-centered ethnography" has been used in psychological anthropology and transcultural psychiatry (LeVine 1982, Hollan 1997) to describe an approach to ethnographic research that seeks to understand cultural phenomena through an in-depth understanding of individual experience.

Patient-Oriented Research

Related terms have also been used to describe applied clinical research that specifically aims to impact patients and healthcare systems, for example, in the Canadian Institutes of Health Research's *Canada's Strategy for Patient Oriented Research* (CIHR 2011). According to the Canadian Institutes of Health Research (CIHR), patient-oriented research "refers to a continuum of research, from the initial studies in humans to comparative effectiveness and outcomes research, and the integration of this research into the health care system and clinical practice." It is focused "on the care of patients in the health care system as opposed to research focused on whole populations," and "begins where basic biomedical research and pre-clinical studies end."

Several concepts relate to person-oriented research ethics and our approach of person-oriented research ethics draws on all of them. However, the aim of person-oriented research ethics is broader than the specific methodologies, study types, or specific applications envisioned by each of the above: it refers to a set of questions and considerations in research ethics that can be applied to *any* study involving human subjects, whether they are social/behavioral or clinical studies, and within in clinical research regardless of whether they are at the clinical or pre-clinical levels.

Practical Guideposts for Person-Oriented Research Ethics

Inspired by the literature in clinical ethics and person-oriented research methodologies, including recent reviews (Morgan and Yoder 2012), we propose five practical guideposts for person-oriented research. These guideposts are (1) respect for holistic personhood; (2) acknowledgement of lived world; (3) individualization; (4) focus on researcher-participant relationships; and (5) empowerment in decision. In formulating these guideposts and their connection with person-centered care, we draw heavily on content analyses of the person-centered care concept, especially those by Slater (2006) and Morgan and Yoder (2012). We combine the insights of these reviews with our own expertise in research ethics and review of the literature on person-centeredness and person-orientedness in research. For each guidepost, we first define and describe it, and then illustrate it using key examples from the literature relevant to the research process. For a full list of examples across different aspects of the research (e.g., research design; recruitment, data collection), please consult the detailed Table 1. Although our presentation imposes a structure to the application and illustration of these five guideposts, we acknowledge that they are tightly intertwined and often overlap.

	Respect for holistic personhood	Acknowledgment of lived world	Individualization	Focus on researcher-participant relationship	Empowerment in decision-making
Research Design	• Use community advisory boards to obtain more information about biological, psychological, and social dimensions of participants (e.g., Gross and Fogg 2001; Oviedo-Joekes et al. 2015). • Enact "evidence-based research ethics" (i.e., the empirical assessment of research ethics concerns, see for example Anderson and Sieber 2009) by consulting studies on potential participants' priorities, experiences, and feedback when designing studies (e.g., Founds 2007). • Include outcome measures based on participants' experiences of the recruitment, consent, or research participation process (Kost et al. 2013; Kost et al. 2014), in order to obtain participant feedback on the research design. • Include measures that are important to participants, such as first-person reports of outcome experiences in addition to laboratory results (Winstein et al. 2003).	• Ensure that study designs are "culturally appropriate and not stigmatizing" (Khodyakov et al. 2016). This can be ensured by engaging target communities in research design, as community members will be able to inform researchers about culturally appropriate practices and anticipate potentials for stigmatization (Jacklin and Kinoshameg 2008; Whittle et al. 2010; both referenced in Khodyakov et al. 2016).	• Tailor the order of study components e.g., in what order assessments must be completed, as Davis and colleagues (Davis et al. 2005) suggest in intervention trials of informal caregivers.	• Employ people in the target population as research assistants, as Williams et al. did in their study of UK's direct payment policy for people with intellectual disability (Williams, Ponting, and Ford 2015). This blurring of boundaries between researcher and research participant challenges power imbalances in research. • Include participants or target communities in data analysis to foster a sense of ownership in the research and increase the use of research findings in community practice (Khodyakov et al. 2016). • "Audit" and review characteristics of interpersonal contact in research, both treatment and non-treatment contacts, and their impact on outcomes (Davis et al. 2005). Important information might include who initiated the contact, the amount of time it took, and the content of interaction. This information can be used for training research staff to have these contact conversations by role-playing common interpersonal contact situations, and can be used to refine contact protocols.	• Use alternatives to randomization in clinical trials, e.g., randomize by site not by individual; allow individuals to select their trial group when blinding is not necessary (Gross and Fogg 2001); adapt statistical strategies to control for confounding factors that may arise from these adaptations (Davis et al. 2005). These procedures allow patients more choice in the process. • Empower patients to share in decisions regarding research priorities and research design following a user-driven approach that involves healthcare users in health research, for example through social media or dedicated online platforms (Price, Chatterjee, & Biswas 2014).

	Respect for holistic personhood	Acknowledgment of lived world	Individualization	Focus on researcher-participant relationship	Empowerment in decision-making
Recruitment of Participants	• Consider feedback of potential participants gathered through qualitative research (Founds 2007) or community advisory boards (Gross and Fogg 2001; Oviedo-Joekes et al. 2015) on motivations for participation and participants' risk-benefit assessments and priorities, in order to design recruitment strategies and materials that address the particular needs and characteristics of the target population. • Reconsider protectionist concerns that may lead to the unfair exclusion of vulnerable participants such as people with substance abuse disorders (Anderson and DuBois 2007) and muscular dystrophy (Skyrme 2016). • Use a person-centered care approach in screening visits for clinical trials, as in Oviedo-Joekes and colleagues' (Oviedo-Joekes et al. 2015) study of opioid dependency treatment. These visits include not only screening assessments, but an introduction to the team and the setting, and are "supportive and understanding of the daily struggles applicants had" (Oviedo-Joekes et al. 2015, 7).	• Consider the impact of research participation not only on participants themselves, but others who may be impacted concurrently or retroactively (Halse and Honey 2007). • Consider the influence that others in the potential participant's social network may have on their decision to participate or not (Bell and Balneaves 2015).	• Provide individualized support for participants to access screening visits, e.g., arranging rides to the research center for participants in an addiction treatment study (Oviedo-Joekes et al. 2015).	• Consider the ways in which participants' decisions to take part in a study are impacted by their perceptions of specific researchers, research institutes, or the general archetype of a researcher (Allen and McNamara 2011; Meloni, Vanthuyne, and Rousseau 2015; Bell and Balneaves 2015).	• Use or create online platforms with "matchmaking" functions that connect potential participants to research studies that might interest them (Kaye et al. 2012). This strategy empowers participants to decide to take part in a study proactively. • Help patients to critically reflect upon their decision-making process and values when determining whether or not to provide consent (Sisti and Stramondo 2015).

	Respect for holistic personhood	Acknowledgment of lived world	Individualization	Focus on researcher-participant relationship	Empowerment in decision-making
Retention of Participants	• Reduce participant stress, for example by limiting the number of researchers entering the home at one time and sequencing data collection tasks with the easiest tests first (Robinson et al. 2011).	• Anticipate how study protocols may fit (or not) with participants' day-to-day lives (Founds 2007; Gross and Fogg 2001) and take steps to minimize difficulties to participate, such as meeting at participants' preferred times and places (Robinson et al. 2011).	• Incorporate flexibility in data collection mechanisms, such as in Robinson and colleagues' (Robinson et al. 2011) option for participants to record their own answers or to have the researcher record answers; to read the questions themselves or to have the researcher read the questions.	• Allow time for social niceties such as accepting tea when collecting data in participants' homes (Robinson et al. 2011). • To retain control group members, train staff who engage in non-intervention contacts in a parallel way to how staff are trained for contact with the intervention group (Davis et al. 2005). • Prepare a plan for points of departure involved in the research process, attentive to the role the researcher has played in the participants' life and the potential need to formalize or ritualize a good-bye (Lichtner 2014).	• Practice "process responsiveness" by sharing information about the study on an ongoing basis as it becomes available and ensuring at each stage that participants still want to be involved in the study (Lahman, Geist, et al. 2011; Lahman, Mendoza, et al. 2011).

	Respect for holistic personhood	Acknowledgment of lived world	Individualization	Focus on researcher-participant relationship	Empowerment in decision-making
Consent Forms and Practices	• Consult research on participants' perspectives and understanding of the consent process and preferences regarding alternative processes such as "extended consent" for biobanking research (Kost et al. 2013; Kost et al. 2014; Allen and McNamara 2011; Anderson and DuBois 2007). • Ensure, if using surrogate or proxy consent (i.e., parents, caretakers) is necessary, that the participants themselves agree to the proxy, have the opportunity to assent, and can override proxy consent via dissent (Fisher 2002, 2003a). Alternatively, researchers can consider others included in the consent process not as proxies, but as consent partners identified by the participant to assist in decision-making (Fisher 2003b).	• Be aware of social contexts that may limit decision-making capability, for example, for adults who have learned "acquiescence to authority" as a survival skill in institutional settings (Fisher 2003b; Björnsdóttir, Stefánsdóttir, and Stefánsdóttir 2014; Harris 2003). • As much as possible, allow space for potential participants to consult with family members or other support persons before deciding to participate (Skyrme 2016). • Consider risks and benefits not only to participants but also the community at large (Khodyakov et al. 2016). • Exercise "structural competency" to be aware of "oppressive factors that may be adversely affecting patient capacity, choice, and, ultimately, health" (Sisti and Stramondo 2015).	• Include structured assessments of consent capacity for each individual (Lichtner 2014). • For participants with impaired decision-making, consult with those close to the potential participant, such as family caretakers or staff (Lichtner 2014). • Consider the option of "witnessed consent" in situations where signed consent may be dangerous for some participants, for example when including undocumented immigrants in research (Lahman, Mendoza, et al. 2011).	• Acknowledge consent as an ongoing process in which consent conversations may need to be revisited multiple times (Lahman, Geist, et al. 2011; Lahman, Mendoza, et al. 2011).	• Proactively include strategies to increase decision-making abilities for participants with potentially reduced decision-making capabilities or limited experience in the research process, for example by providing opportunities to "practice" decision making before the consent form review and demonstrating the lack of negative consequences for saying no (Fisher 2002, 2003a, 2003b; Björnsdóttir, Stefánsdóttir, and Stefánsdóttir 2014). • Consult toolkits for writing accessibly (Ridpath, Wiese, and Greene 2009) and use instruments for measuring the quality of informed consent (Judkins-Cohn et al. 2014). • Include options to present consent information in accessible ways (e.g., Braille, large print, ASL, spoken & written) (Sheldon and Ferris 2010; Björnsdóttir, Stefánsdóttir, and Stefánsdóttir 2014; Fisher 2003a).

	Respect for holistic personhood	Acknowledgment of lived world	Individualization	Focus on researcher-participant relationship	Empowerment in decision-making
Consent Forms and Practices (Continued)	• Avoid holding vulnerable populations to a higher standard of competency than the general population by excessively scrutinizing the competency to consent of vulnerable populations, particularly with respect to the standard that participants must engage in "rational manipulation of information." Too strict an application of this standard may lead to overuse of proxy decision-makers and deny the agency of the participant (Fisher 2003b).				• Supplement consent forms with audiovisual material (Anderson and DuBois 2007; Fisher 2002). • Respect the "healthy mistrust" of research expressed by participants who are "actively attempting to understand the research process and not simply signing over their rights in ignorance" (Lahman, Geist, et al. 2011). • Accept participants' decision-making strategies as rational, even if they differ from the risk-benefit analysis conducted by researchers or research ethics committees (Allen and McNamara 2011). • Reaffirm consent at the end of a study (Björnsdóttir, Stefánsdóttir, and Stefánsdóttir 2014).

	Respect for holistic personhood	Acknowledgment of lived world	Individualization	Focus on researcher-participant relationship	Empowerment in decision-making
Dissemination	• Use descriptive, non-judgmental, and non-stigmatizing language when describing participants in research reports (Lahman, Geist, et al. 2011; Anderson and DuBois 2007; Khodyakov et al. 2016). • Involve community members in the dissemination of results to help research knowledge and evidence-based treatments reach community settings (Khodyakov et al. 2016). • Tailor dissemination to particular target audiences. For example, the *British Journal of Learning Disabilities* includes "accessible summary" abstracts aimed at readers with learning disabilities (Williams, Ponting, and Ford 2015).	• Focus on not only "bench to bedside" but also "bench to curbside", i.e., knowledge translation to community settings, following the principles of community-engaged research (Khodyakov et al. 2016).	• When appropriate, provide personal research results to individual participants (Cordner et al. 2012).	• Broadly and quickly report summary results when applicable, for example at ClinicalTrials.gov, to show respect for participants who assumed the risk of participating and to honor the "social contract" participants enter into when joining a study (Doernberg and Wendler 2016).	• Empower participants to access the results of the study (Lahman, Geist, et al. 2011), for example through open-access data sharing platforms (Dyke et al. 2015).

1. Respect for Holistic Personhood

One of the key features of person-centered care is "respect for holistic personhood." Morgan and Yoder describe this feature as being "respectful," in the sense of recognizing patients as "consumers" with the right to make decisions about their treatment and their daily care routines; as well as the characteristic of being "holistic," in the sense of recognizing biological, social, psychological, and spiritual aspects of the person and their interdependence (Morgan and Yoder 2012). While the configuration of patients or research participants as consumers has been problematized (McLaughlin 2009), this guidepost nonetheless similarly focuses on the role of potential research participants as agents capable of and entitled to contributing in many ways beyond consenting to research and offering their data or tissues. Relatedly, Slater (2006) identifies "recognition of personhood" as a key concept in person-centered care, in the sense of understanding the present world of patients and offering choices even in situations (e.g., dementia) where decision-making might be difficult.

These characteristics show clear connection with classical principles of research ethics. "Respect for persons" is a cornerstone of research ethics and endures throughout all aspects of person-oriented research ethics described in this section. Respect for persons is generally understood to integrate the principle of respect for autonomy in research participation and is the primary reason participants need to give informed, voluntary consent, assent, and/or dissent (United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1978). Respect for *holistic* personhood moves one step further in the direction of inclusiveness, asking whose autonomy is considered and in what ways. The term

"personhood" is often used in a legalistic sense in debates about who "has" or does not "have" it, i.e., who is considered to be a person upon whom rights and responsibilities are bestowed (Csordas 1994), for example regarding the issue of "fetal personhood." In contrast, respect for holistic personhood maintains that the recognition of all participants' personhood, even participants with potential or actual impairments of decision-making capacity (Slater 2006), is a dynamic process contingent on the action of persons involved in a situation (Demertzi et al. 2013, Pilapil 2012). This principle involves a strengths-based approach that focuses on capability and values the potential contributions of individuals to research questions that concern them (Lahman, Geist, et al. 2011).

In the research context, the guidepost of respect for holistic personhood applies less to patients and treatment processes, and more to potential participants and research processes. In short, person-oriented research recognizes value in the contributions of all potential research participants, even those in situations of vulnerability. Person-oriented research is designed to respect and take into consideration the contributions of research participants by soliciting feedback of the target population and designing the research process to take into consideration needs, preferences, or priorities that might impact persons in this population.

There are many ways researchers can respect the holistic personhood of participants (summarized in Table 1). To illustrate this guidepost in action, we will pull from the SALOME study of opioid dependency treatment by Oviedo-Joekes and colleagues (2015), with particular attention to the way that these researchers infused their study with respect for holistic personhood. First, these researchers formed a community advisory board of various stakeholders in order to create a space for discussion about the study and obtain feedback about study procedures and ethical issues informed by the community. This is a common strategy in more

person-oriented studies (see also Gross and Fogg 2001). Drawing on previous qualitative research with target populations can also help inform researchers in this way (Founds 2007). Second, Oviedo-Joekes and colleagues also explicitly used a person-centered care approach in screening visits for clinical trials. These visits included not only screening assessments, but an introduction to the team and the setting, and are "supportive and understanding of the daily struggles applicants had" (Oviedo-Joekes et al. 2015:7). These strategies demonstrated respect for holistic personhood by considering needs that may be specific to the target population as well as providing a research environment that was respectful, holistic, and caring to individual participants. Notably, these participants were illicitly using opioid medications and therefore might have been considered especially vulnerable in the research process. However, respect for holistic personhood entails recognizing the contributions and capacities even of the most vulnerable research participants. While participants in the SALOME study signed their own consent forms, not all research participants are deemed capable of doing so (for example, legal minors, some participants with intellectual disabilities). Respect for holistic personhood entails particular attention to participants in these situations, who might otherwise be overlooked on the assumption that a proxy consent is sufficient. It requires ensuring that the participants themselves agree to the proxy, have the opportunity to assent, and can override proxy consent via dissent (Fisher 2002, Fisher 2003a). Alternatively, researchers can consider others included in the consent process not as proxies, but as consent partners identified by the participant to assist in decision-making (Fisher 2003b). A particularly important consideration is to avoid holding vulnerable populations to a higher standard of competency than the general population by excessively scrutinizing the competency to consent of vulnerable populations, particularly with respect to the standard that participants must engage in "rational manipulation of information."

Too strict an application of this standard may lead to overuse of proxy decision-makers and deny the agency of the participant (Fisher 2003b). Overall, strategies that align with this guidepost are those that focus on treating potential participants as agents and taking into consideration the specific needs, strengths, and preferences of target populations.

2. Acknowledgement of Lived World

Respect for holistic personhood focuses primarily on the present world of individuals, but person-oriented research ethics also acknowledges the many external factors that influence that present world. The guidepost of "acknowledgement of lived world" draws researchers' attention to such factors and how they might influence the research process. This guidepost derives from the person-centered care concept of "acknowledgment of the person's lived world," in the sense of considering the impact of past or present experiences and the role of the environment (Slater 2006). This guidepost brings attention to the factors that influence participants' needs, including individual, family, and community beliefs, norms, and values (Morgan and Yoder 2012), as well as a recognition of the researcher's beliefs, norms, and values and how they may impact the research encounter (Slater 2006). It stresses protocols and procedures that are culturally appropriate and non-stigmatizing (Khodyakov et al. 2016). It includes, as relevant to the research topic and individual participant, present, past, and even future experiences (Slater 2006), and awareness of the role of family and friends and the potential need or desire for their involvement in decision-making (Morgan and Yoder 2012).

Acknowledgement of lived world is also closely tied to the classic research ethics concept of autonomy, specifically a relational or contextual perspective on autonomy. In common research ethics guidance, "autonomous" participants are those who make individual,

independent, rational decisions (Allen and McNamara 2011). A person-oriented research ethics approach recognizes autonomy as more complex relational and contextual property. It includes an awareness of the relational and contextual aspects of autonomy, which is not the exercise of an isolated rational self but rather a self embedded in social context (Ells, Hunt, and Chambers-Evans 2011; Racine et al. 2017; Racine and Dubljevic 2016, 2017; Mackenzie and Stoljar 2000). Interpersonal relationships may play an important role in individuals' experiences – including both relationships with the provider/researcher and relationships with family members who may be involved directly or indirectly in the research process or decisions about research. In person-centered care, this might mean "collaborating with others to enable, support, and not impede a patient's autonomy" while recognizing that "some relationships and involvement of others can impede a particular patient's autonomy, or otherwise be undesirable from a particular patient's perspective" and therefore inclusion of significant others should be done only after assessing how the patient feels about this involvement (Ells, Hunt, and Chambers-Evans 2011). While it is important to acknowledge the relational nature of autonomy and the importance many individuals and cultures place on relational, interdependent autonomy, this is not to romanticize relational autonomy to the exclusion of individual autonomy. Individual autonomy must continue to respect individual rights "and among these rights, […] the right to renounce individual autonomy in favor of other important values such as […] trusting in a good physician, family relations, the authority of medical science, and so forth" (Turoldo 2010). Relational autonomy is not limited to individual interpersonal relationships; the relational perspective on autonomy also includes a recognition of relationships with "the whole structure of society" (Ells, Hunt, and Chambers 2011), including systematic forces such as oppression that influence decision-making.

Being guided by acknowledgement of lived world in the research process means considering factors outside of the research setting itself which may impact research. This could be personal factors such as the beliefs, norms, values, life situations, and personal relationships of actors (researchers, participants, regulators, and others). It also means considering the historical context in which a research study is being conducted (what research has been done on this topic before and how has it impacted key communities) In short, person-oriented research considers the role of social context and significant others in the participants' life.

Table 1 again summarizes various ways researchers can enact this guidepost. Here, we reference the suggestions offered by Khodyakov and colleagues (2016) for ethical community-engaged research. First, they emphasize that study designs should be "culturally appropriate and not stigmatizing" (Khodyakov et al. 2016). This can be ensured by engaging target communities in research design, as community members will be able to inform researchers about culturally appropriate practices and anticipate potentials for stigmatization (Jacklin and Kinoshameg 2008; Whittle et al. 2010; both referenced in Khodyakov et al. 2016). Second, they stress the necessity of being forthcoming about study risks and benefits as well as considering and communicating risks and benefits not only to participants but also the community at large (Khodyakov et al. 2016). This practice reflects the interrelatedness between individual participants and broader communities. Finally, the community-engaged approach advocated by these authors focuses on not only "bench to bedside" but also "bench to curbside," meaning knowledge translation to community settings, following the principles of community-engaged research (Khodyakov et al. 2016).

While community-engaged research focuses on the relationship between researchers and broader communities, the guidepost of acknowledgement of lived world also addresses more

microsocial interactions. Other day-to-day suggestions for researchers include ensuring potential participants can consult with family members or other support persons before deciding to participate, if they wish (Skyrme 2016), and minimize social or structural barriers to participation through strategies such as meeting at participants' preferred time and place when possible (Robinson et al. 2011).

3. Individualization

Acknowledgment of participants' lived worlds involves knowledge about cultural and social factors that may influence research participants. Nonetheless, these factors should not overshadow the importance of individual variation. A key component of person-centered care is that it is individualized. It provides customized care based on an understanding of the individual's situation including life history, culture, beliefs, traditions, and personality (Morgan and Yoder 2012). Accordingly, the guidepost of individualization stresses the consideration of the unique needs of each person, but without reduction to characteristics of the population, be it diagnosis, ethnicity, gender, or religion. As much as possible given the study design, research should be open to individualization that takes into consideration the unique needs of specific individuals beyond simply providing attention to the general needs of a particular population (e.g., a particular patient group). In short, person-oriented research provides a toolkit of strategies for involving participants inspired by their patient population or cultural characteristics, but not a checklist that reduces them to such characteristics.

As mentioned above, individualization poses perhaps the most notable feasibility challenge in certain research contexts. Some methods (e.g., semi-structured qualitative interviews) are intentionally flexible and open to individual variation between participants and

data collection sessions. While other methods intentionally require consistency in order to control for confounding variables. Perhaps most notable is the gold standard randomized controlled trial. Lest the reader think our suggestions are applicable only to qualitative, ethnographic, or participatory research, we dedicate the example in this section to a randomized intervention trial for informal caregivers (Davis et al. 2005).

Davis and colleagues (2005) conducted a community-based randomized trial involving people who served as unpaid caregivers for other community members. They report on three participant-centered adaptations they used in their trial, which aimed at responding to participant needs, minimizing participant attrition rates, and exploring treatment effectiveness in real-world conditions. Some of these adaptations fall under the guidepost of individualization. Notably, Davis and colleagues reported tailoring the order of study components (e.g., in what order training sessions and assessments must be completed) based on participant needs and stress levels. They identified other studies which had used similar customizable orders. Changing the order of study components between participants might raise concerns about standardization, central to the design of controlled trials. However, Davis and colleagues accounted for such concerns by applying two analytical strategies for tracking and controlling potential confounds related to tailored interventions. First, the order of components or time spent on each component was monitored and included in analysis. Second, group characteristics that differ between different component orders were included as covariates in order to statistically control for any group differences. For full details on Davis and colleagues statistical strategy, we refer the reader to the full text (Davis et al. 2005).

4. Focus on Researcher-Participant Relationships

Research is a social and interpersonal endeavor, whether or not the researcher and the research participants interact directly (e.g., biobanking; online or mailed survey research). Person-centered care focuses heavily on the relationship between providers and patients (Morgan and Yoder 2012; Slater 2006). Studies in person-centered care recognize an imbalance of power in this relationship, which traditionally favors the provider. A person-centered approach to care, in contrast, favors more of a partnership type relationship (Slater 2006). Person-oriented research parallels this attention to provider-patient relationships with a focus on researcher-participant relationships. This guidepost brings attention to the power dynamics involved in research. Within the research ethics literature, these power dynamics are perhaps most evident in discussions of vulnerability (Bracken-Roche and Racine, under review). While the regulatory research framework often suggests that vulnerability is an innate characteristic of members of certain high-risk groups, a person-oriented approach understands vulnerability as the result of relationships and contexts (Bell et al. 2014). Attention to researcher-participant relationships also relates to building and maintaining trust and rapport between researcher, participant, and participant community (Anderson and Rorty 2001, Khodyakov et al. 2016), and to strategies that reconfigure the relationship between researcher and participant by including people from the target population as research assistants (Williams, Ponting, and Ford 2015) or in data analysis (Khodyakov et al. 2016). In short, person-oriented research considers carefully the relationship between researchers and participants and how it is shaped by sociological, economic, and political factors.

There are several ways researchers can take researcher-participant relationships into consideration across the research process (detailed in Table 1). Some of these suggestions encourage researchers to reflect on how they are perceived by participants. For example, several

studies consider the ways in which participants' decisions to take part in a study are impacted by their perceptions of specific researchers, research institutes, or the general archetype of a researcher (Allen and McNamara 2011, Meloni, Vanthuyne, and Rousseau 2015, Bell and Balneaves 2015). Additionally, researchers stress the importance of the social relationship established in research and encourage researchers to allow time for social niceties such as accepting tea when collecting data in participants' homes (Robinson et al. 2011), and to prepare a plan for points of departure involved in the research process, attentive to the role the researcher has played in the participants' life and the potential need to formalize or ritualize a good-bye (Lichtner 2014).

Other suggestions aligned with this guidepost challenge the traditional relationship between researcher and research participant, blurring the boundaries between them and challenging the power imbalance of research. For example, Williams, Ponting, and Ford (2015) employed people with intellectual disabilities as research assistants in their study of the UK's direct payment policy for this population.

5. Empowerment in decision-making

Empowerment is a final important component of person-centered care that can be applied to the research process. Empowerment supports patients' self-determination and decision-making abilities through sharing information, supporting choices, and using effective communication (Morgan and Yoder 2012). Regulatory research ethics focuses on participant decision-making primarily in the context of the consent form review, where participants must decide whether or not to participate in research. The important considerations in regulatory research ethics are *information, comprehension,* and *voluntariness* (United States National Commission for the

Protection of Human Subjects of Biomedical and Behavioral Research 1978). According to person-oriented research ethics, these considerations are not all-or-nothing. Rather, the capacity to make informed, voluntary decisions is understood as a skill that can be encouraged and fostered (Racine et al. 2017). Therefore, person-oriented research ethics draws on person-centered priorities of autonomy, self-confidence, and self-determination – and how to enhance them (Morgan and Yoder 2012). Moreover, the person-oriented research ethics approach recognizes the call to practice "process consent," in which the consent conversation is seen not a singular event in which a form is signed, but as an ongoing process which is revisited over the course of the study (Lahman, Geist, et al. 2011). In short, person-oriented research includes strategies to maximize the decision-making abilities of potential participants.

There are several ways researchers can empower participants in decision-making (Table 1). We here focus specifically on the suggestions by Björnsdóttir, Stefánsdóttir, and Stefánsdóttir (2014) in their study of adults with intellectual disability. This study is particularly useful for understanding some of the ways researchers can incorporate empowerment in decision-making into their studies. People with intellectual disabilities are often considered particularly vulnerable in the research process. They often face barriers with respect to empowerment in decision-making and the opportunity to speak for themselves and provide their own assent to participate (see also Fisher 2003b). Björnsdóttir and colleagues proactively included strategies to increase decision-making abilities for participants with potentially reduced decision-making capabilities or limited experience in the research process, for example by providing opportunities to "practice" decision making before the consent form review and demonstrating the lack of negative consequences for saying no (see also Fisher 2002, 2003a, 2003b.). Information about the study was provided using accessible language in both written and spoken formats.

The researchers also reaffirmed consent at the end of a study during a member checking phase as part of data analysis (Björnsdóttir, Stefánsdóttir, and Stefánsdóttir 2014). This suggestion empowers people to choose whether or not to participate in research. Other suggestions for empowerment in decision making include empowering people to choose *how* to participate in research. For example, in clinical trials, some scholars have suggested allowing participants to select their trial group when blinding is not necessary (Gross and Fogg 2001; see also Veatch 1987). Others have stressed the importance of empowering participants to choose the direction of research, for example through user-driven study design (Price, Chatterjee, and Biswas 2014). These examples show that deciding whether or not to participate in research is not the only moment of decision-making researchers can address.

Limitations

Person-oriented research ethics offers an approach to incorporate ethical thinking and practice concerning everyday and interpersonal aspects of the research process, but we need to acknowledge its current limitations. For example, so far, its tenets have been generated from literature reviews, discussion papers, and ethical analyses but have not been validated based on stakeholder input. Focus groups or task forces with researchers and potential research participants would strengthen this framework and lead to suggestions for tailoring it to specific research participant populations or specific methods or aspects of the research process. This is a process in which the authors are currently involved for research involving participants on the autism spectrum (Cascio, Weiss, and Racine 2017). Furthermore, the framework is limited by virtue of its breadth. Not every suggestion listed in Table 1 is applicable to every study. Strategies for experimental trials, such as alternatives to randomization, will not necessarily be useful for observational or interview-based studies. Suggestions for observational or interview-

based studies, such as collecting data in the time and place of participants' choice, may not be possible in experimental trials requiring specific equipment and settings. Including participants in data analysis may be possible with some types of data but impossible to accomplish with other types of data due to the risk of breaching confidentiality (e.g., interview transcripts where participants would be indirectly identifiable to other participants, such as when multiple family members participate) (Cridland et al. 2015). Although participant-centered outcome measures are important within certain trends of patient-oriented research, such outcome measures may not be able to answer certain research questions, for example, in some types of basic research. Disseminating results back to participants may be complicated by participants being lost to follow-up. Even for recommendations that would fit well with a particular research project, there may be limits in practicality and feasibility especially due to funding and resource limits. For example, the use of audiovisual material in the consent process may require equipment and personnel not available to all research teams. Despite these limitations, the practical guideposts of person-oriented research ethics can be an aspiration in every study. Individual researchers and research teams will need to use their best judgment in determining which of the strategies suggested above fits best with their research objectives.

Conclusion

Researchers' experience and understanding of research ethics often amount to a view that equates research ethics with a regulatory paradigm, involving limited aspirational pull and limited attention to everyday and interpersonal issues encountered in research. This paper presented a person-oriented research ethics approach for studies involving human subjects to complement this understanding and experience of research ethics. The suggestions supporting the guideposts of person-oriented research ethics reviewed in this paper derive from literature in

clinical and research ethics and can serve as a toolkit that researchers can draw from in designing and undertaking their studies, across the research process in ways that are respectful, holistic, individualized, relational, and empowering. Research ethics board members could use this framework to assist in evaluating proposed studies. Studies informed by person-oriented research ethics have the potential to include more participants ethically and meaningfully in research, from inclusion criteria to recruitment to retention, and therefore produce results that are more robust and more applicable to target populations. A person-oriented research ethics approach takes into consideration the specific issues that participants may be likely to experience while remaining flexible to individual variation in participants' symptomatology and experience. We hope that ethics scholars will find the person-oriented research ethics useful for its synthesis of literature applying clinical ethics concepts such as person-centered care to the research process and its ability to operationalize it to support researchers and research ethics boards. Future research should attempt to specify — in partnership with stakeholders — the specific contours of person-oriented research ethics in different clinical and societal contexts.

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