



Ethics is for human subjects too: Participant perspectives on responsibility in health research



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ABSTRACT

Despite the significant literature as well as energy devoted to ethical review of research involving human subjects, little attention has been given to understanding the experiences of those who volunteer as human subjects. Why and how do they decide to participate in research? Is research participation viewed as a form of social responsibility or as a way of obtaining individual benefits? What if anything do research subjects feel they are owed for participation? And what do they feel that they owe the researcher? Drawing on in-depth individual interviews conducted in 2006 and 2007 with 41 subjects who participated in a variety of types of health research in Canada, this paper focuses on subject perspectives on responsibility in research. Highlighting the range of ways that subjects describe their involvement in research and commitments to being a 'good' subject, we present a typology of narratives that sheds new light on the diverse meanings of research participation. These narratives are not mutually exclusive or prescriptive but are presented as ideal types typifying a set of circumstances and values. As such, they collectively illuminate a range of motivations expressed by human subjects as well as potential sources of vulnerability. The typology adds a new dimension to the literature in this area and has significant implications for researchers seeking more human-subject centred approaches to research recruitment and retention, as well as research ethics boards trying to better anticipate the perspectives of prospective participants.

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"Ethics is not only for the researcher, [it's] for the people participating in the research too, you know."

Healthy female, biomedical research, HS804.

Introduction

A growing literature in research ethics now includes the perspectives of human subjects alongside those of scholars, researchers and members of research ethics committees. Publications such as the recently established *Journal of Empirical Research on Human Research Ethics* feature articles on subjects' experiences of research participation. Overall, there is increasing attention to topics such as reasons for or against participating (Albrecht et al., 2003) satisfaction with informed consent procedures (Corrigan, 2003), comprehension of risks (Kass & Sugarman, 1996), views on compensation (Hampson et al., 2006) and sources of trust or

mistrust in the research enterprise (McDonald, Townsend, Cox, Lafrenière, & Paterson, 2008). Fewer studies focus on understanding the meanings that human subjects themselves give to their research participation, whether these might differ from the taken-for-granted assumptions of researchers and members of research ethics boards (REBs) and, if so, how a more accurate understanding of human subjects' perspectives might inform an evidence-based approach to ethical review and oversight (McDonald & Cox, 2009). A salient finding is that human subjects do not tend to conform to models of the researcher–subject relationship suggested in the literature but rather, "move through multiple roles and identities as part of the navigation through unfamiliar social territory, in order to establish a relationship in which they can feel socially comfortable and appropriately valued" (Morris & Balmer, 2006: 998).

Language is a powerful arbiter of social reality. Hence a central issue in the scholarly literature is how the human subject is socially constructed in and through the discourse of academic research ethics as well as the actual process of research. Is the term 'human subjects' demeaning? Is 'volunteers' a more neutral and hence acceptable term? Or, given the growing importance of participatory

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research design, should the human subject more properly be referred to as a 'research participant' (Corrigan & Tutton, 2010; McDonald & Cox, 2009). Such matters should be considered in light of the constraints associated with the roles available to participants within the context of specific kinds of research design (e.g., a randomized clinical trial versus community-based participatory action research) (Cox, Ross, Townsend, & Woodgate, 2011).

Emphasizing the fluidity of researcher–subject relationships and the meanings that participants give to their participation in health research, this paper focuses on the question of responsibility and how it is constructed in and through human subjects' experiences of research participation. In particular, we draw upon what was a key insight for us, namely that many human subjects identify in the experience of research participation a form of active ethical engagement. As the human subject quoted above says, "ethics is not only for the researcher".

Ethical engagement manifests for human subjects in the felt need to identify and articulate the underlying moral basis for their participation as well as the pragmatic orientations they experience toward researchers and the research process. Possibilities for the 'human subject' to actively negotiate shifting roles and relationships with researchers are therefore taken up, modified or declined according to human subjects' values and life circumstances (Morris & Balmer, 2006). These tacit dimensions of being a research participant are rarely addressed in the literature. Moreover, the routine practices of ethical review involve imagining what is likely to occur for research participants but not learning from what actually occurs (Stark, 2012).

This paper reflects on participant responsibility as a means of gathering together and distilling some overlooked aspects of the experiences of human subjects. The outcome of our analysis is a set of story types. These offer fresh insight into how human subjects conceptualize their participation in health research including how they articulate a sense of agency or powerlessness and how they identify specific values associated with their participation.

Research design and methods

The research reported here was part of the first phase of a larger three-phase project titled *Centring the human subject in health research: Exploring the meaning and experience of research participation (2005–2011)*. Designed with the aim of surfacing a wide range of experiences and ethical concerns arising from biomedical, clinical, behavioural and other types of health research, phase I of the study entailed in-depth interviews with human subjects, researchers, Research Ethics Boards (REB) members and scholars/policymakers. Drawing on in-depth interviews conducted with 41 human subjects during this first phase of the study, we focus here on the theme of responsibility. Although we agree with Corrigan and Tutton (2010) that use of the term "subject" may convey a more passive stance than "participant", we have for pragmatic reasons opted to use the term "human subject" to refer to those who participate in health research and "participant" to refer broadly to all those who took part in our larger study.

Recruitment and study participants

We recruited 41 human subjects for our phase I interviews. To obtain heterogeneous sample in terms of demographics, health status and the type of health research, we used a variety of recruitment strategies: poster and media advertisements in a range of publications and health related settings; opportunistic sampling (through social and network connections), and consultations with relevant communities. All participants took part in at least one semi-structured interview (37 face-to-face and 4 telephone).

Our sample included 23 women and 18 men ranging in age from early 20's to late 70's. Participants came from a range of ethnic backgrounds, but all were English speaking. At the time of their initial participation in a health research study 16 reported they were healthy, 11 reported being acutely ill, and 23 indicated being chronically ill. Of these 41 participants, 39 reported volunteering for one or more health research projects. For the sake of clarity, we have classified them according to the health studies that were most salient in their discussions: clinical studies (20), behavioural studies (9), basic biomedical studies (7), and public health studies (3). One participant did not complete the interview, but is included as the interviewer had been in contact for a substantial period of time and had recorded field notes of their conversations. One participant reported declining to take part in two separate health studies, and another participant reported declining to take part in one health study.

Interview approach

Prior to initiating the interviews for Phase I we developed an interview guide based on a series of open-ended questions. This guide included six broad areas asking participants to: 1) describe details of the research studies they had been involved in as human subjects; 2) discuss their decision(s) to become involved in these studies; 3) reflect on their understanding of the risks, benefits and more generally the overall experience of being involved in these studies; 4) consider what being a human subject meant to them; 5) offer their views on broader issues such as levels of trust in research or how well human subjects are protected; and 6) query any aspects of our 'Centring the Human Subject' study they were curious about. Probes for these areas were listed on the interview guide but participants were invited to tell their story according to their own style and conventions. Interviews were conducted by two researchers (including SMC) and two research assistants (NP and SH) who were members of the research team. According to the individual participant's preferences, interviews were conducted in a university meeting room, local community centre, or the participant's home. They lasted for 45–90 min. All interviews were audio taped with permission with a follow-up phone call as necessary to clarify points raised in the interview.

Discussion of the informed consent process preceded each interview and sometimes elicited relevant commentary from the participant about their prior experiences with informed consent forms while participating in other studies. With permission, we recorded these discussions and treated them as part of the data.

Process of analysis

The recorded interviews were transcribed verbatim. Transcripts were checked for accuracy. Analysis was conducted in several stages. One of us (SMC) initially began this work with a research assistant (NP) who did many of the interviews. At this early stage we adopted a constant comparative approach based on grounded theory strategies of open and axial coding as well as memoing (Charmaz, 2006; Strauss & Corbin, 1994;) on a wide range of topics. NVivo software was used to facilitate coding and subsequent analysis of emerging themes of trust, relationships, reasons for participation and risks and benefits. When the theme of responsibility began to emerge as a salient new concept that was related to, but distinct from, the reasons that participants reported as relevant to their decision to participate in a health research study, we adopted an alternative strategy for analysis. At this point, an additional research assistant (SH) participated in the analysis and took the lead in recoding the transcripts according to our newly emergent ideas. It appeared to us at this point that fracturing the data into thematically relevant chunks for the purpose of coding was detracting from our ability to both see and learn how to think with

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