

## **Why We Need to Keep the Term "Research Subject" in Our Research Ethics Vocabulary**

**By Elisa A. Hurley**

We are in the midst of momentous changes in the field of human research protections, and not just significant regulatory changes, although that may be front and center in our minds right now. We're also navigating some larger conceptual shifts in what this enterprise called "human subjects research" is, and what it looks like. Some of these shifts are coming about because of the settings in which a lot of research now takes place — in the "real world" and "usual care settings," on the Internet and social media, and in the cloud. We're also, as a field, invoking some newer or additional research ethics principles, beyond the big three: respect for persons, beneficence and justice — principles like transparency, trust, engagement and reciprocity — and we're asking whether, given the realities of the contemporary research landscape, whether these principles should be incorporated into our core research ethics framework.

Another conceptual shift in play, related to this last point, is around our terminology for the individuals who enroll in research: whether they are "research subjects" or "research participants."

Some suggest that it is time to jettison the term "research subject" altogether, including in the regulations, and exclusively use the term "research participant." There are a number of compelling arguments for this wholesale move from "subject" to "participant":

- "Participant" is more respectful and more consistent with recognizing people's autonomy.
- It reflects a general shift across the research enterprise toward patient engagement and embraces the principles of transparency and reciprocity.
- It signals a welcome move away from outdated notions of paternalism and protectionism — the idea that a research subject is someone who is acted upon and in need of protection from manipulation, rather than someone with the agency to actively choose to participate in research for their own reasons.
- It counteracts lingering distrust in the research enterprise and in researchers, especially among communities of color, and maybe even helps foster much-needed public trust in and support of research.
- And, finally, it signals how far we've moved beyond the troubled history of research at its most exploitative — the Nazi experiments, Tuskegee, Willowbrook, Guatemala — episodes in which vulnerable people were treated as passive subjects, as human guinea pigs, for the sake of science.

Most recently, the National Academies report, "Returning Individual Research Results to Participants," included a short but compelling articulation of the argument for moving from "subject" to "participant" "across the board"<sup>1</sup> — in fact, that is what got me thinking more about this issue.

There is a lot that is attractive in this idea of giving up the term "research subject" once and for all. Of course, we want to demonstrate respect for research volunteers. Of course, we don't want to be overly paternalistic. Of course, we welcome and embrace the principles of transparency and reciprocity. Of course, we want to cast off the darker history of research abuses. And, of course, we recognize that people *are* engaged in research in ways that were unimaginable 40 or 50 years ago, when this terminology was put in place. Research *is*

different now. So, isn't this a good time to give up the term "research subject" once and for all?

My answer is no. I believe that such a move would be a mistake, and that we need to keep both "research subject" and "research participant" in our shared vocabulary.

Consider this: We're all accustomed to being careful about when and where we refer to someone as a "patient," and when we refer to her as a "subject or participant." And I imagine we're all familiar with the *reasons* for being careful. We know using the word "patient" in the research context would be misleading; it has specific connotations that poorly fit that context. Specifically, it suggests the intervention the person is receiving is designed and delivered for her own therapeutic benefit, and that decisions by the physician will be based only on what is in her best clinical interest. Neither of these conditions are, of course, accurate in the research context, where decisions about interventions are driven by standardized protocols designed to answer pre-determined scientific questions. Calling the person a "patient" might sound more caring, more familiar, and less scary, but that's irrelevant when we want to communicate, for instance in an informed consent form, that we're asking the person to enroll in *research*, and what that means for her.

I want to suggest it's equally important to be careful about our use of research "participant" and "subject" because, here too, each of these words has specific connotations, which may or may not be fitting to what is actually happening in a particular research context, and may or may not be fitting in ways that matter for thinking about research protections.

Let's look at the term "participant." In a nutshell, calling someone a research "participant" signals or suggests a kind of active and ongoing engagement in a shared endeavor. Beyond engagement, it suggests the individual has some ownership or investment in the research project in question, or in its outcomes or findings.

Traditionally, the organization I lead, Public Responsibility in Medicine and Research (PRIM&R), has chosen not to use the word "participant" in the research context, on the grounds that it obscures real power and knowledge asymmetries between researchers and those upon whom research interventions or procedures are done, or about whom information is being collected. These asymmetries are endemic to just about all research. Using the term "subject" to refer to those who volunteer for research, on the other hand, makes salient these asymmetries and people's position of relative vulnerability within the research enterprise. It also highlights the need for independent mechanisms to ensure that those who volunteer for research are respected and protected, and that's been my default position as well.

But, over time, I've been persuaded that, as long as we recognize that "participant" doesn't mean "equal partner," referring to those who are enrolled in research as "participants," *is* probably appropriate for many circumstances.

For example, I think about patient-centered outcomes research projects that successfully engage research volunteers in decision making at various points in the research process, from determining the research question or weighing in on study design, to helping with recruitment and interpreting research results. Or I think about longitudinal observational field work or participatory action research conducted in communities with a high incidence of disease, research methodologies that depend on the establishing long-term, trusting relationships between researchers and those they're learning from. Or, I think of studies that involve, from the outset, plans to communicate to participants aggregate or individual research results during the course of or following completion of the study. These scenarios strike me as cases in which using the term "participant" *would* be appropriate because they are characterized by ongoing engagement of the participant in the project. These projects have the characteristics of a shared endeavor.

But there are other circumstances in which using the term “participant” might not be fitting, and, in fact, risks understating or even obfuscating important characteristics of the research, thereby providing a false sense of the agency exercised by the subject or lulling us into complacency about the need for protections.

Consider so-called “big data” research. A lot has been written about how big data research — research that uses and analyzes large data sets to understand and predict various aspects of human behavior — is complicating the very idea of human subjects research. I’m going to set aside the question of which big-data research is actually “human subjects research” under our current regulatory framework and continue my current line of reasoning.

In this context, large quantities of data that are collected by social media sites, search engines, and other applications — sometimes highly sensitive data, such as information about people’s sexual orientation or health status — are stripped of personal identifiers and made available for other uses, including for academic research. To take one prominent example, the Social Science Research Council and Facebook recently announced a partnership whereby Facebook would release large amounts of de-identified proprietary data to academic scholars to facilitate their research on issues like the impact of social media on elections and politics.<sup>2</sup>

Obviously, there a lot of issues here, and I am not going to explore the ethics of big data research here. For my present purpose, the important point is that large amounts of personal information are being gathered from people every day and increasingly being made available for research. Although the information in these large datasets is de-identified and often publicly available, much of this research involves aggregating multiple primary data sets, significantly increasing the chance of reidentification and, thereby, raising privacy concerns.

It is off the mark to call the people whose data is collected, combined and used in these ways — that is, basically, all of us — research “participants.” This is the case regardless of whether we think the terms of service we accept adequately constitute informed consent. If we think about what “participant” connotes — ongoing, active engagement in a shared endeavor, a level of ownership and buy-in — that’s just absent here.

On the contrary, I would argue, as have others, that in many of these cases, we have become research subjects,<sup>3</sup> whose private, potentially identifiable or re-identifiable information is being tapped for research. And further, there are risks that our information is being used in ways that we don’t want, or getting into the wrong hands, leading to dignitary or other harms. Referring to people in these contexts as “research subjects” is not disrespectful. Rather, it importantly indicates that we have little or no agency in these situations and are vulnerable to these risks. It highlights the fact that, in this research domain, people are involved, but are not actively engaged, and that we should, therefore, pay special attention to what protections are needed.

Is big data a unique domain? Maybe, but I doubt it. But in any case, I raise the example because I think it highlights why it would be premature to jettison “subject” from our research ethics vocabulary and framework. The term “subject” has a role to play: It makes salient important features of some research contexts, or more to the point, important features that are missing from these contexts.

I worry that a wholesale move to using research “participant” across the board amounts to a shortcut way to feel satisfied about the level of information, engagement or power granted to individuals who enroll in research. I worry about use of the term “participant” to rationalize skipping the work of actually engaging these individuals as true stakeholders in the project.

Maintaining an appropriate sense of responsibility for doing this work is why we need to keep both terms, “subject” and “participant,” in our vocabulary.

I’d also like to suggest that there are conditions that must be met in a research project before it would be appropriate to refer to those who enroll as “research participants.” The obligation for meeting these conditions falls to the researchers, and maybe the research sponsors. When they have done the work of informing, involving, engaging and sharing with those who enroll in research, then they, and we, have earned the right to refer to these individuals as “research participants.” I’m suggesting here that we reserve the term “research participant” for a kind of achievement.

The question of what specific conditions need to be met for someone properly to be thought of as a “research participant” merits further exploration, beyond what I can do here. I imagine it will vary by project. For some projects, say a large clinical trial, where the scale of the study won’t allow for more robust types of engagement, it may be enough that, in addition to involving a quality informed consent process, information is shared with participants throughout the study, including in the form of aggregate results at the end. But for other study types, where more robust forms engagement, such as requesting participant feedback on various aspects of the study, from design and recruitment strategies to methods for returning results, are feasible, the bar for considering someone to be a research “participant” might be higher. These questions are worth exploring further. My point is that the right to use the term “research participant” must be earned by making the appropriate efforts to actively engage volunteers in the research.

So then, we might ask, if it’s not the case now that everyone enrolled in research is appropriately referred to as a “participant,” should that be our collective goal? Or are there some research contexts that, by their nature, can only involve people as “subjects”?

Let’s return to big data. Is thinking of people as research “participants” achievable in this domain? Perhaps, if we could imagine a world in which there is, first and foremost, transparency about this research, and where everyone is aware that their data is collected and of the uses to which it might be put. Some scholars have imagined a future in which we own our data, can opt out of its being used, or can share it with whom we want, on our own terms, thereby controlling how our information is used and maybe the risks to which we are exposed.<sup>4</sup> In this scenario, “research participant” might very well be fitting.

But that’s a pretty high bar. And it brings us back to the question I previously asked: Should a research enterprise where all those involved in research are appropriately thought of as “participants” be our collective goal as research ethics professionals?

This is a fascinating question. And, if it is our goal, it raises further interesting questions about what we would have to do to reach it. To start with, we would have to do a much better job educating the public about research as a collective, public good.

To conclude, I want to make a plea for keeping both research “participant” and research “subject” in our shared vocabulary. The term “research subject” is not one we can just jettison — no matter how well meaning the desire to do so might be — but one we must grapple with as we reimagine our responsibilities as research ethics professionals.

## References

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### **Author**

Elisa A. Hurley, PhD, is Executive Director of Public Responsibility in Medicine and Research (PRIM&R). Contact her at [ehurley@primr.org](mailto:ehurley@primr.org).