

Commentary on Zvonareva et al.: Exploring the many meanings of “professional” in research participation

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I once heard on a movie one time, ‘The first time you took money, you became a professional.’ So I guess I was a professional. From the first time I accepted money for the service [of being a healthy research participant], I was a professional.

—Participant from HealthyVOICES Project¹

Within the field of bioethics and among many clinical trialists, the term “professional” has come to have a very specific meaning when referring to research participants. As highlighted by Roberto Abadie’s book *The Professional Guinea Pig*,² the focus is largely on those participants, particularly healthy volunteers, who enroll in clinical trials as though it were their full-time job. In contrast, the excellent article by Zvonareva et al.³ illustrates that the term “professional” can be interpreted in multiple ways that differentially attend to who enrolls in clinical trials and how they perceive their role as research participants. Drawing upon the sociology of professions,^{4,5} Zvonareva et al. are particularly interested in the specialized knowledge and skills that healthy volunteers acquire through their clinical trial involvement, making them highly reliable—and thus valuable—participants. By learning what is expected of participants during Phase I clinical trials, healthy volunteers can dramatically support the workflow of trialists who must adhere to highly rigid procedure schedules, such as timed dosing of investigational drugs and blood collection. Zvonareva et al. demonstrate that when healthy volunteers adopt a positive work ethic toward their contribution to clinical trials, they engage in a type of identity work⁶ that allows them to see value in the contribution they are making to science beyond the financial compensation they receive. However, Zvonareva et al. also note that healthy volunteers are not formally credentialed or certified, so unlike traditional professions, they have limited power and no prestige conferred by their professionalizing activities.

That research participants cannot quite meet the sociological definition of professionals perhaps begs the

question of how are we to best understand what the term does and should mean when it comes to those who enroll in clinical trials. In my own collaborative work on participation in Phase I trials,^{7,8} we asked healthy volunteers whether they considered themselves to be “professional” study participants. By exploring their views on the topic, something of a consensus around the criteria that define a professional emerges, including receiving financial compensation, having experience and specialized knowledge, and exerting control over one’s work, and these themes are worth brief exploration. As might be expected, some participants evaluated whether they were professionals based on treating their clinical trial enrollment as a job. For example, one participant stated, “Yeah, it was bringing in the income. That was my current employment, was being there [in the research clinic], you know, and getting a check after completing the study.” Similarly, those who had other employment typically said they could *not* be professionals because clinical trials were not their sole work or their primary source of income.

However, those participants who did not have other work did not automatically default into the identity of being a professional. For them, other factors such as frequency of participation and the extent of trial involvement were more salient than a mere paycheck from clinical trials. Because many healthy volunteers have quite low income, clinical trial compensation can easily make up the bulk of the annual income they earn from any source.^{9,10} Thus, study income mattered less to some participants than how often they enrolled in studies, with many claiming that professionals are those “hardcore” people who join studies as often as they can. The distinguishing characteristic differentiating those who participate regularly from those who are

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professionals often came down to how far people would travel to enroll in studies.¹¹ For example, one participant explained,

These guys travel. All of them that are pros, they travel all over the United States. Me, I only been to three places over here [in my region] ... These guys, they get on planes, and they still might not get in [the clinical trial]. You gotta be a pro to do that and keep that going.

Experience and knowledge were also critical pieces of how healthy volunteers determined who should be considered professional participants. Having been enrolling in studies over a long period of time was a piece of the equation, but more important was the individual's comfort with the clinical trial process. This idea particularly comes across in the words of one participant:

[Initially,] I was nervous as shit ... and I asked a thousand questions. ... You know, I was a rookie. I was wet behind the ears, you know, [laughs] it was before I turned professional. ... But as time went on and I started doing more studies, I got used to it, and I got used to how everything works and needles and getting stuck—you know, blood draws and all that. ... It just became part of being at the [research] facility. I already knew, you know, what was going to happen, so ... I was not as nervous.

Part of this experience was also taking on the role of guiding or socializing new healthy volunteers to the clinic routines. Some participants claimed that they became so familiar with the operation of clinical trials that they could practically work as research staff at the clinics. As the quote above illustrates, professional participants are those who might be more comfortable with clinical trial risks but they also asserted that professionals have the knowledge to choose less risky studies. Even more importantly from the perspective of healthy volunteers, professionals know how to improve their chances of qualifying for the next clinical trial. For example, a participant asserted,

When you're [a] professional, you're trying to make sure you're making [i.e., qualifying for] these studies. ... You know, [you] find out, "Okay, your iron was too low." "Hmm, well, why is my iron low?" And then you start researching. That's when you start being professional, because now you're trying to make sure you actually make the study every time and not even have to worry about any [blood] levels or anything, you know? ... That took time, you know, in learning and observing and asking questions.

This kind of knowledge about their bodies and what is required to qualify for a study certainly can be seen

through the lens of professions in which individuals gain experience and expertise over time in their field, even for research participation.

Of course, healthy volunteers cannot fully control their research participation in that they are subject to the availability of studies and cannot always regulate their physiological state in order to qualify for new studies. This issue of control was a part of healthy volunteers' perceptions of whether or not one could ever be a professional participant. For those who felt they could exert control over their participation, they were more likely to identify as professionals. For example, a participant who claimed this label said he did so because,

You're an independent contractor, for one thing ... [and] you can turn down a study any time. You can turn it down when you screen, just say, "No, I don't want it," after being consented. ... You can actually be entered in, and at the last minute ... before they put the needle in you or [you] take the pills, and [you can] say, "No, I don't want to do it." So that's your power that you have with that.

Despite healthy volunteers' engagement with the term "professional," the question of semantics arises. Specifically, what term or terms do healthy volunteers themselves prefer to use when referring to their own status as research participants? While "professional" certainly came up unprompted over the course of interviewing healthy volunteers, the term to which they seemed to gravitate more was "veteran." This alternative framing of their experience through what one could see as a military analogy downplayed the financial dimension in their identity construction. One participant described his preference for the term: "A veteran means like old-school ... We just call 'em 'veterans' cause they've been through it and they know all the routines and so when they go through it [a study], they know it's a cinch." One participant rejected the term "professional" because of the unwarranted prestige he thought it conveyed to research participation:

I never thought, "Oh yeah," you know, "I'll do one [study] after another, and I'll make this my life's purpose. [sarcastically] I am a professional drug trial participant." ... [sarcastically] I can see myself with my cape, you know, flying around and stuff. No, I never thought of that. [sarcastically] "Oh, my parents are proud of me. I'm a guinea pig." ... No, but, I mean, like, people put themselves on a pedestal and be like, "Oh, I'm a professional." [sarcastically] Yeah. Not from participating in drug studies. Definitely not.

Returning to Zvonareva et al.'s³ article, attention to the positive work ethic that research participants might bring to their clinical trial involvement is much needed.

Our research has also shown that healthy volunteers narrate the importance of professionalism, such as being organized, well-informed, and polite while in the research clinic.¹² In contrast, the literature has largely focused on the “subversive” and “deceptive” behavior of participants, particularly those who are motivated by financial incentives to enroll.^{13–16} This focus is propelled by a concern about individuals who jeopardize the research enterprise or themselves when they disregard the rules of their participation (e.g. inclusion–exclusion criteria or study restrictions). This is an important line of inquiry, but Zvonareva et al. provide empirical evidence to suggest that there might be many more research participants who take seriously their commitment to follow the rules and facilitate clinical research. Their work offers a needed reminder that “professional” need not be a dirty word.

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