

# Informal professionalization of healthy participants in phase I clinical trials in Russia

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## Abstract

**Background:** Previous social science research has shown how some healthy phase I trial participants identify themselves as workers and rely on trials as a major source of income. The term “professionalization” has been used to denote this phenomenon.

**Purpose:** We aim to examine a component of healthy trial participants’ professionalization that has not yet been systematically studied: how repeat phase I trial participants develop and claim expertise that distinguishes them from others and makes them uniquely positioned to perform high-quality clinical trial labor. We also aim to explain the significance of these research results for protection of healthy participants in phase I trials.

**Methods:** This qualitative exploratory study was conducted in Russia, in two phase I trial units. It involved semi-structured interviews with 28 healthy trial participants with varying lengths of experience in trials, observations of work done in trial units, and interpretive conversations with investigative staff.

**Results:** Interviewed healthy individuals who repeatedly participate in phase I trials describe developing knowledge and skills that involve appreciating the meaning of trial procedures, coming up with techniques to efficiently follow them, organizing themselves and others in the course of a trial, and sharing tacit ways of doing trial work well with other less experienced participants. Our results suggest that a prerequisite for such expertise-centered professionalization is the emergence of a positive identity linked to seeing value in trial participation work. A crucial component of professionalization thus understood is the development of a work ethic that entails caring about results and being reliable partners for investigators.

**Limitations:** The attitudes and behaviors presented in this article are not suggested to be universally shared among healthy trial participants, but rather represent a particular instance of professionalization that coexists with other views and tactics.

**Conclusions:** A way of better protecting healthy trial participants begins with recognizing their skills, knowledge, and the centrality of the contribution they are making to pharmaceutical research. Currently, the expertise of experienced trial participants is recognized on the work floor only; therefore, the professionalization we described is informal. Yet, the informal professionalization process is inherently risky as it does not involve any change in the formal conditions of trial participants’ work. Instituting formal measures for protecting healthy trial participants as skilled workers combined with recognition of their expertise is essential.

## Keywords

Professionalization, informality, phase I, trial participants, healthy volunteers

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... it takes the human research subject to a higher level of civilization when he or she looks in the mirror and sees the face of a specialized worker, whose craft has its own wondrous history, its own jargon, and its own weird little culture.

—Robert Helms, editor of the journal for human research subjects “Guinea Pig Zero”<sup>1</sup>

Sizable numbers of healthy individuals repeatedly enroll in phase I pharmaceutical clinical trials.<sup>2,3</sup> Scholars have used the term “professional” to describe their regular participation and reliance on trials as a major source of income.<sup>4,5</sup> In this article we explore repeat participation in phase I trials in Russia, to contribute to answering a long-standing question: how to understand the role of healthy participants in pharmaceutical research?

Ways to ensure protection of these individuals hinge on how their role in pharmaceutical research is defined. “Volunteers” is the term firmly entrenched in the language of bioethical guidance.<sup>6</sup> When healthy trial participants are defined as volunteers, protecting them primarily involves ensuring the voluntariness of their consent to enroll in a trial.<sup>7</sup> The vast literature that takes trial participants to be volunteers has stressed how the voluntariness of consent is threatened by undue influence, conceived, broadly, as an incentive that can be unwelcome or difficult to resist.<sup>8</sup> Undue influence has become of such a paramount concern among ethicists and regulators that the debate on protecting healthy trial participants has focused mostly on the amount the payment should be, in order to avoid unduly inducing healthy individuals into enrolling.<sup>9</sup>

At the same time, this orthodoxy has been criticized as it produces a different kind of problem, namely the problem of exploitation.<sup>10</sup> The specter of exploitation arises because efforts to avoid undue influence can work to offer inadequate compensation to trial participants for the burdens assumed, and to divert attention from how trial participants are treated.<sup>11</sup> Bioethicists who voice these concerns define the role of healthy trial participants as workers and argue that “research studies on healthy subjects—unlike research on sick patients—are best characterized as a kind of labor relation.”<sup>12</sup> When healthy trial participants are defined as workers, concern with voluntariness remains but is broadened to include issues of fairness and justice. Protection of such workers can rely on labor rights, including worker compensation schemes, collective negotiation, oversight of working conditions, and minimum wage (equivalent, as Shamoo and Resnik<sup>13</sup> suggest, to the wage paid to unskilled laborers).

This article explores empirically the role healthy individuals assume in phase I trials in Russia and focuses on the knowledge and skills they bring into the process of trial conduct. Previous social science research has questioned how realistic is the identification of healthy participants as volunteers, considering that healthy

individuals’ leading motive for participation is financial<sup>14</sup> and some of them actually view trial participation as their job. For example, Abadie<sup>5</sup> explored ethnographically how “professional guinea pigs” in Philadelphia, in the United States, conceived of themselves as contractual workers, and Monahan and Fisher<sup>4</sup> illustrated entrepreneurial ways in which healthy individuals, also in the United States, maintained their competitiveness in the job market of trial participation. Yet, this body of research has not examined the development of specific expertise by healthy trial participants as a part of their professionalization. In this article, we show how repeat phase I trial participants develop and claim special skills and knowledge that distinguish them from others and make them uniquely positioned to perform high-quality clinical trial labor. Our analysis draws on the insights from the sociology of professions, which has examined how members of professional groups rely on the special character of the knowledge required to perform their tasks to distinguish themselves from those of other occupations.<sup>15–17</sup> We aim to explain explicate the significance of our research results for protection of healthy participants in phase I trials.

## Methods

This qualitative exploratory study was conducted in Russia, in two phase I trial units. One of these units is located in a large city in the western part of the country, and the other is in a smaller city in the east. Both units are a part of public organizations involved in research and healthcare provision. Data collection took place between June 2013 and June 2017 and primarily involved semi-structured interviews with 28 healthy clinical trial participants (Table 1). These individuals were either present at the trial units at the time of data collection and agreed to participate in the interview, or agreed to be contacted by members of this study team after being asked by trial investigators. All of them signed an informed consent form. Of those who participated repeatedly, all but 1 reported enrolling in trials exclusively in one and the same trial unit.

### Data collection and analysis

Interviews with trial participants were focused on their motivations, experiences, and expectations in trials. In

**Table 1.** Informants (N = 28).

Gender	
Women	9
Men	19
Clinical trial experience	
1 study	13
2–4 studies	5
5–10 studies	7
>10 studies	3

the course of the interviews, the informants were also encouraged to bring up issues related to trial participation that in their opinion were relevant. The interviews were conducted by O.Z. and I.P. until the point of saturation was reached—that is, no new themes relevant for understanding participation of healthy individuals in pharmaceutical research surfaced during the interviews. The interviews were conducted in Russian, audio-recorded, and transcribed verbatim. Data collection also involved informal conversations with investigators to solicit their perspectives on the instances and practices described by trial participants. Data collection necessitated multiple visits to the trial units, during which the study team became familiar with the units' infrastructure and were able to observe interactions between trial participants and investigators. Insights from informal conversations and observations were written down in fieldnotes immediately after each trial unit visit.

Over the course of data collection, data analysis and interpretation were continuously performed. The interviews and notes were read and discussed regularly by all members of the research team, and the issues that required further exploration were identified. Drawing on the transcripts of the first interviews, O.Z. and I.P. jointly developed the preliminary coding scheme for labeling the text units that referred to one or several concepts relevant for the purpose of this study. Codes were altered and added throughout data collection, with the input of all team members, as more interviews were conducted and more field notes were written. Analytical themes were developed by gathering together the codes of related content. A theme of professionalization emerged early in the analysis process. It was selected as a core focus due to its prominence, and analysis centered on the codes related to the value of trial work, role and expertise of trial participants, and work ethic. When a disagreement over a code or interpretation arose, the team reflected on divergences and agreed on their representation in the manuscript.

The emphasis in this study was on discovering a range of views and experiences and also on eliciting a range of patterns of thinking rather than establishing their prevalence. Because of the qualitative nature of the data and the relatively low number of interviewees, frequencies are indicated in broad terms (i.e. a few, some, all).

### ***Ethical considerations***

This project was approved by the Ethics Committee of National Research Center for Preventive Medicine (Protocol 02-05/13). The confidentiality of the respondents was ensured by the separation of data from individuals' identities, the secure storage of the codes linking data to individuals, and anonymizing the

individuals in this article. No compensation was provided to the informants.

### **Results**

Three major themes emerged from the analysis of the collected data. This section presents them, with illustrative quotes, in the following order: first, we describe how healthy participants in phase I trials construct positive identities for themselves; second, we delineate the kinds of skills and knowledge they claim to be developing in the process of trial participation; third, we elaborate the work ethic that stems from their perspectives on the nature of healthy trial participants' job. Together these themes outline the contours of an informal professionalization process among some repeat healthy participants in clinical trials in Russia.

To set the stage for presenting our results, we briefly outline the context from which these results originate. In 2017, 700 permissions for conducting clinical trials were given by the Russian Ministry of Health. It is estimated that about one third of these 700 permissions were for trials with healthy individuals.<sup>18</sup> Most organizations licensed to conduct clinical trials are located in Moscow and Saint Petersburg; the vast majority of these are large, public organizations, such as state research clinics and hospitals. The individuals who were trial participants in the two phase I trial units where this research was conducted usually learned about enrollment opportunities either from Internet advertisements or from friends. Many were students searching for temporary jobs or young professionals interested in obtaining additional income. A few were unemployed, and for them trials were a source of income to get them through "tough times." Furthermore, a few were health professionals invited to participate by their colleagues.

### ***Positive identity***

The perspectives of interviewed healthy participants outline the specific capacity in which they approach interaction with the commercial pharmaceutical trials enterprise: as professional workers who create value with their labor. They invariably referred to the societal contribution made through enrollment in trials. Although the vast majority admitted, straightforwardly, that their primary motivation to take part in trials was financial, it appeared important for them to conceive their actions, in the words of one of our informants, as "doing something valuable." A common specification of the value of healthy trial participants' work referred to protecting future patients from harmful substances. A statement of a man, reflecting on his first clinical trial experience, is illustrative of this reasoning:

Imagine, drugs are not tested and just immediately begin to be produced and sold, this all might have very sad

consequences. So if they did not check this drug and immediately it was introduced in pharmacies and people used it, then, God save, people might become sick or something worse ... That's why I think I did good. (1H, male, 1 trial)

While healthy trial participants were aware that they were not the only ones who took experimental drugs in the process of pre-market testing, they still considered their part important.

The quote presented above came from a person who at the time of the interview just completed his first trial. Establishing a positive identity from the very beginning of a long-term involvement in drug testing turned out to be atypical for healthy individuals we interviewed. More common was a gradual development of positive identity as exemplified by another informant who narrated that, at the beginning of his involvement in clinical trials, he would call himself a guinea pig. Not anymore. After prolonged trial involvement he explained that trials are a “world-wide practice and there is no progress without it” and explicitly denied being guinea pig: “it has nothing to do with guinea pigs, you sign informed consent and you know what you are agreeing to and where you are going” (1F, male, 5 trials). This perspective stresses a changing degree of perceived control over one's work: from a guinea pig having no control to a professionalizing worker who asserts more control over their decisions and activities.

This story of a gradual formation of a positive identity of a healthy trial participant highlights two details. First, unprompted, several of our informants denied being “guinea pigs” when discussing their role in clinical trials, since for them the term appeared to be stripping them of their agency and denying value to their contribution.<sup>1</sup> Second, appreciation of the value of trial participation work arises gradually in the process of involvement in clinical research through searching for additional information about trials and drug development reported by many of the interviewed trial participants and through socializing with other trial participants. The latter tends to happen, at least initially, during their stays at trial sites. For example, one serial trial participant recalled a conversation that triggered a change in his views on clinical trials participation:

So one girl said “I think we all are so great, we are researching new drugs.” I responded: “let's be honest, you are here because of money.” She said: “yes, because of money, but I see other positives as well.” So I feel the same way now. (O16, male, more than 10 trials)

Overall, an absence of a contradiction between being motivated financially and seeing value in one's work came to the fore in the interviews with healthy individuals who repeatedly participate in clinical trials. They

would not make themselves available for drug testing without receiving payment, yet they perceived what they do as having social value and, usually gradually, developed a positive identity as workers performing a necessary job.

### *Skills and knowledge*

Many trial participants who have extensive experience in trials described developing a set of knowledge and skills that makes them “better” workers and that also can be shared with the newcomers. This development usually begins with becoming interested in research itself and acquiring more information about the goals and practices of clinical trials. The word “interesting” was often used by informants to indicate a trigger that stimulated them to “look at all this in detail” (1J, male, 3 trials).

Closer familiarity with clinical research brings greater appreciation for trial procedures, which tend to be highly regimented in trials with healthy individuals. For example, occasions for administration of experimental substance and blood testing are tightly scheduled and have to be performed precisely as planned, without delays and interruptions. Experienced trial participants contrasted the period at the beginning of their involvement in trials with latter stages, when they “began understanding better, what they [investigators] are doing here, for which purpose it all is needed” (1I, male, 6 trials). A typical account stressed not caring much for anything but receiving payment at the beginning. Trial participation at that initial stage would consist of coming to the trial site, doing “something,” and getting paid. Then through getting interested in the trial process itself, a contrasting attitude can emerge with characteristic attention to the meaning and quality of trial procedures. For example, an already quoted experienced male trial participant described the following development trajectory, which is presented here in detail to illustrate the attitude change:

During my first trials I did not really think about it. Now I am thinking. For example, I need to describe some effect. Have dizziness—have to tell. If there is any pain—have to tell. ... I still try to take into account if something is happening to me, if there are any changes. During the first trials even if something was happening to me I never told anyone about it. I thought—everyone is silent, and I will keep silence. Now I do not think like this. Now I think differently. (1I, male, 6 trials)

Experienced participants also eagerly explained the importance of following dietary and regime restrictions for producing reliable research results.

Apart from identifying ways to produce quality data, with time healthy trial participants tend to develop other less tangible skills as well. These skills have to do

with planning and filling their time during trials, efficiently following routines and technological procedures, and dealing with instances of discomfort such as prolonged periods of immobility. While no healthy trial participant was able to put their finger on exactly what this “learning to do things” consists of, investigators agreed that there was much difference between how trials run depending on the number of experienced participants involved. The higher this number, the less concern investigators tended to have regarding the smooth running of study protocol and unexpected events.

Generally, many experienced healthy participants in this study felt that by becoming more knowledgeable about trials and more skilled in their trial work they are able to improve the quality of their contribution in the research and, ultimately, the quality of the results produced. Also common was an intention not only to focus on one’s own individual work but also to support and instruct newcomers. As one trial participant put it: “As an experienced volunteer I explain everything to new ones” (1F, male, 5 trials). The value of such explanations can be illustrated by a statement of a participant interviewed at the end of his first trial: “guys were supporting—they explained many things, because many of them were participating not for the first time, so I had people around to ask how to do things right” (1H, male, 1 trial). In this first-time trial participant’s experience, learning was required to do a healthy trial participant’s work “right” and it was the other participants who provided guidance for this.

### Work ethic

Seeing value in clinical trials and in trial participation, interviewed healthy participants tended to develop ideas about “proper conduct” associated with their role. Many spoke about a sense of responsibility for their own contribution and the effect it makes on the overall trial results. This sense of responsibility developed in conjunction with the described positive identity in the course of prolonged trial involvement. However, there were exceptions, such as a single mother who was looking for a temporary source of income and at the time of the interview was finishing taking part in her very first trial. She started off by saying she “liked payment very much; with this sum of money you can really buy something and live for a while.” Later on, and of her own accord, she proceeded to raise the topic of responsibility in her narrative: “So being healthy I want to help in drug research, so this aspect is important for me as well ... I take this with great responsibility for this research to be really helpful” (1D, female, 1 trial). In the reasoning of this, and other trial participants, the possibility of conceiving their work as societally beneficial was dependent upon the quality of the job they were doing.

This described conception of responsibility to a wider society was also complemented by feeling responsible to trial investigators. Some interviewed trial participants proposed a mutual division of labor in running phase I clinical trials where investigators constantly monitor the state of participants and participants conscientiously follow trial procedures. Illustrative here is a monologue of one experienced trial participant who said it is important that

us [trial participants] do not let down investigators. There were cases when some people possibly secretly smoked in the toilets or something else. It is a pity. ... I think investigators are doing their work, a hundred percent. But volunteers sometimes do a shoddy job, it is not good. (O16, male, more than 10 trials)

This emphasis on making a quality contribution to a common good, on the one hand, forms a part of a claim for recognition of a specialized and valuable character of a trial participants’ labor, put forward by informants in this study. On the other hand, this notion of responsibility can easily be co-opted by more powerful players in the pharmaceutical trials industry for making trial participants more exploitable. We will return to this latter argument in the discussion.

Apart from taking on some responsibility for the reliability of trial results, during the interviews other qualities desirable of a healthy trial participant were brought up as well. For instance, several participants mentioned punctuality. Often trial participation is not limited to a single hospital stay but rather requires multiple visits. To avoid interrupting the trial flow and wasting other people’s time, several participants made it a point to be on time. Few interviewed participants considered patience a necessary quality. Patience in their opinion was necessary for maintaining a “good atmosphere” during trial visits that involve sitting or lying down and “doing nothing.” In response to such conditions, one can become resentful and begin complaining, or help themselves and others by being patient. Finally, common was an assertion that a healthy volunteer should, above all, be healthy. Those who were of this opinion mentioned a healthy lifestyle in terms of nutrition, being physically active, and limiting alcohol and smoking, as important for being able to “cope” with a trials work. Illustrative here is a reflection of an investigator who in a separate conversation called a popular perception of healthy participants as “somewhat anti-social” “totally wrong,” and stressed their adherence to a healthy lifestyle to be prepared to perform a trials work at any time.

### Limitations

The results presented here were obtained from a specific setting, which calls for certain limitations to be

considered when interpreting them. First, both phase I trial units we focused on were of a similar type—part of public research and healthcare organizations—and for-profit trial units are not represented. Second, both units were located in the same sociocultural context, in Russia, albeit in different parts of the country. Finally, our data were collected from a relatively small number of healthy trial participants, among whom we focused on those who participate repeatedly. However, our intent was to explore in detail a specific instance of professionalization of healthy individuals' participation in clinical research, and this study allowed us to do so. This instance diverges markedly from how professionalization of this group has been described so far and invites further research on the reasons behind this divergence.

## Discussion

In this article, we explored how individuals who repeatedly participate in phase I clinical trials in Russia define their role and contribution. What came to the fore in this exploration is a process of informal professionalization of trial participants. Let us, first, elaborate on what professionalization entails in this case. Previous studies of healthy trial participants have tended to use the term “professionalization” to refer to repeat participation and reliance on trials as a primary source of income. They also have tended to focus on such behaviors as concealment, rule-breaking, and deception by experienced trial participants.<sup>4,5</sup> In contrast, we use the term “professionalization” to highlight development and claims to specialized knowledge and skills among healthy trial participants in the course of involvement in trials. These knowledge and skills involve appreciating the meaning of trial procedures and developing techniques to follow them efficiently, organizing themselves and others in the course of a trial, and sharing tacit ways of doing trial work well with less experienced participants. Our results suggest that a crucial component of professionalization thus understood is the development of a work ethic that entails caring about results and being reliable partners for investigators. A prerequisite for professionalization thus understood is the emergence of a positive identity linked to seeing value in trial participation work.

The instance of identity construction described in this article is not universally shared. It was not universally shared in the settings where our study was conducted as our informants' statements, cited in the “Work ethic” section, illustrate (“volunteers sometimes do a shoddy job”). It is also far from being universally shared in other settings, as Roberto Abadie's book *The Professional Guinea Pig*<sup>5</sup> illustrates. Abadie describes how healthy trial participants “both comply with the trial demands and resist them whenever they can” (p.

6). Yet, recent research conducted in the United States illuminates mindsets and practices among healthy clinical trial participants similar to those found in our study. An investigation of adverse events reporting found that rather than subverting trial results in an attempt to prevent the termination of trial participation and the associated loss of earnings, healthy trial participants were mostly willing to forgo their full compensation when believing that not reporting adverse events “jeopardizes their own safety or the validity of the research.”<sup>19</sup> In addition, another article reports on fairly common reflections among healthy trial participants on the importance of the possible societal benefits of their participation.<sup>20</sup> We can discern, then, the coexistence of a variety of attitudes and behaviors among healthy trial participants in different settings, whereas it is the subversive and rule-breaking practices that have received the most attention in scholarship on repeat trial participation to date.<sup>21–24</sup> Attention to specialized knowledge and skills, bound together by work ethic offered in this article, allows for a different way of defining what it means to be a professional trial participant. A way that focuses not on skills in rule-breaking, or making a living from research participation, nor so much on a number of trials as such, but on the expertise and value trial participants bring to biomedical knowledge production.

The understanding of professionalization as having to do with the development of expertise that is claimed to make a group of people uniquely suited to perform a certain type of work is in line with scholarship in the field of the sociology of professions.<sup>15–17</sup> Yet, there is a particularity in the process of professionalization among some healthy trial participants in Russia we outlined. The sociology of professions scholarship stresses the relationship between claiming expertise and securing market monopoly and higher social status.<sup>25–27</sup> This relationship unfolds through such strategies as building a body of specialized knowledge and education programs, building associations, and establishing codes to standardize technical expertise and work ethic, employed by a group of people aspiring to establish or strengthen their professional status.<sup>28–30</sup> However, in the case of healthy trial participants this relationship is rather informal, as specialized knowledge, skills, and work ethic are developed and used in the process of trial conduct. The expertise of experienced trial participants is recognized on the work floor only, where investigators appreciate their efficiency, self-organization, and patience in following burdensome procedures. Trial participants who were informants in this study attempted to “corner the market” by appealing to their specialized ability to perform high-quality trial work. However, recognition of this ability is not secured by anything other than relationships with investigators.

What do these results mean for protecting healthy participants in phase I trials? To find a starting point

for answering this question we can, again, turn to the work of Abadie<sup>5</sup> who suggests that subversive actions by clinical trial participants such as “introducing forbidden food or attempting to disrupt trial regimens” arise due to participants being “resentful of the depersonalized, humiliating, and alienating treatment they often receive” (p. 6). Our results are reminiscent of what Nancy King Reame<sup>31</sup> articulated a while ago: “Besides agonizing over the morally acceptable level of payment, we need to get more creative about ways to make research subjects feel valued.” A way of doing this begins with recognizing healthy trial participants’ skills, knowledge, and the centrality of the contribution they are making to pharmaceutical research. At the same time, it is important to prevent co-option of this agenda. A large body of scholarship has demonstrated that trial participants engage in labor under casual and precarious conditions shaped by the vastly profitable enterprise of drug development.<sup>32–35</sup> Simply touting healthy trial participants as valuable members of research teams will only make it all too easy to extract their labor without any change in the background conditions. In this sense, the informal professionalization process is inherently risky as it does not involve any change in the formal conditions of trial participants’ work. It is essential to combine recognition of healthy trial participants’ expertise and their contribution with the institution of formal measures for protecting them as skilled workers, such as the provision of adequate wages, controlling working conditions, and the establishment of compensation schemes. This approach contrasts starkly with some arguments put forward in bioethical scholarship suggesting that not only can trial participants not be considered skilled workers, but they cannot be considered workers at all.<sup>36</sup>

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