Exotic guinea pigs at home: An ethnography of professional research subjects in the US

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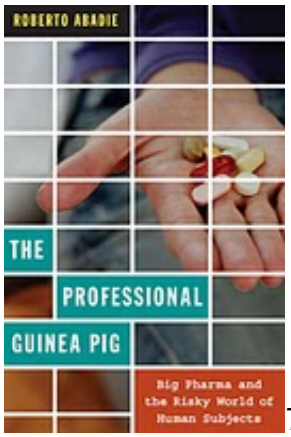
By



This post was contributed by Roberto Abadie (CUNY)

A few years ago anthropologist Michaela di Leonardo invited anthropologists to focus on what she called "exotics at home". Her intention was to re-center anthropological inquiry, shifting the discipline's emphasis on "the other", often living in remote cultures, to groups living among us, right at home. Di Leonardo reminded us of the need to look at domestic sources of power, wealth, and inequality in an attempt to understand how they might affect the everyday lives of numerous groups and institutions that had remained until then, hidden, invisible, their suffering untold. That's what I have tried to do with my ethnographic study of healthy paid subjects earning a living testing drug safety in Phase I Clinical Trials, *The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects*, recently published by Duke University Press. This research took place in 2003 and 2004 in Philadelphia –a hotbed of clinical trial activity conducted by such Pharma giants as Merck, AstraZeneca, Pfizer and Bristol Meyers among others- during 2003 and 2004.

I realized that although bioethicists have discussed the ethics of offering financial compensation to healthy paid subjects, there was not a single empirical study about them. For example, we didn't know who they were, or what motivated them to participate in the trial economy, how they made decisions about joining particular trials, or about risks they might face. And we had no idea about what it feels like to be a human guinea pig, how they experienced their trial participation and how they talked about the trials. To

find out, I decided to live with a group of healthy paid subjects in an area of West Philadelphia. This group, mainly comprised of white men, had a very visible guinea pig culture, with its own professional Zine *Guinea Pig Zero*, a job-magazine describing their participation in the trials from the perspective and interests of the professional guinea pigs. In addition, some professional guinea pigs self defined themselves as anarchists with a very strong view of the Pharmaceutical Industry and governmental regulation. I was aware that this would be an unusual sub-population of professional guinea pigs, who overall tend to be poorer, less educated, and overwhelmingly from minority groups. Still, I felt confident that their experiences as professional subjects would be a window into the social organization of clinical trials and the place financial compensation played in recruiting, retaining and controlling trial subjects. I lived among them, following them to the trials, to their trial screenings, the appointments, witnessing their trial preparations and tribulations.

One very important piece is the Informed Consent Form subjects sign at the beginning of the trial spelling out the trial design, goals and potential risks. I wanted to understand how much they knew about the risks they would face and how much they cared about them. So I asked them many questions about the Consent Form they had signed. Financial compensation can reach up to $400 a day for an in-patient trial and these trials usually can last between two to four weeks. I therefore worried that paid subjects would neglect to consider certain risks in their willingness to obtain the financial compensation. And I was also concerned that the large sums of money would be use to coerce professional guinea pigs both to join the trial and to remain in it.

This ethnography is the first empirical study of professional research subjects testing drug safety, not only in the US but also elsewhere. It is important not only because it has not been conducted before, but because it focuses on the emergence of a professional group that plays a central role in drug development, a multibillion dollar industry that is one of the cornerstones of our health care system.

Drugs are first tested in animals and if they are safe they are then tested in a small group of human beings to make sure they will be safe for human consumption during Phase I Trials. If a drug is proven to be safe then is further tested, partly for safety but mainly for efficacy, to prove that it would be effective in Phases II and III. Until 1970 drug safety was tested in prisoners but concerns over their capacity to give proper, un-coerced consent brought the practice to a halt. The Pharmaceutical Industry stood to lose billions if drugs coming down their research pipelines could not be tested. Pharma started offering payments to potential recruits and initially the unemployed, unemployable, students, artists, part-time workers and others showed up. Some could not withstand the boredom, the discomfort

and the dehumanizing treatment as trial subjects and never showed up again. But some stayed and were lured with phone calls, mailing ads and other aggressive recruiting tactics. These subjects became used to the role of trial subjects and the industry became in turn dependent on professional, dependable and compliant research subjects. A new profession emerged: the professional research subject.

This ethnography is also a study of the historical and social forces behind these transformations as well as an examination of the ideology, interests and aspirations of this new professional category brought by a shift from an industrial to a service or knowledge based economy. Most professional guinea pigs I met in Philadelphia had done numerous trials, some more than 80, others even more. Trials had become their full time job. They saw themselves not as “paid volunteers”, as the industry refers to them but rather, as workers, performing a strange type of work, paid to endure the treatment of what Spam, a seasoned guinea pig volunteer and janitor organizer, called the “mild torture economy” of trial participation. Professional guinea pigs perceive most trials as being of moderate risk. Most have not experienced a serious Adverse Drug Reaction even after years of participation and, besides, they reason, the trial is designed as a controlled experiment and supervision is constant. They feel that the Pharmaceutical industry is doing the right thing, not because they care about them but because they fear lawsuits if something goes wrong. Their preferred trials are those that test drugs such as pain killers or gastritis drugs that have already been on the market for some time and thus have been tested by millions of people. The drugs they perceive as riskier are those that are tested for the first time on humans after being tested before only in animals. In the case of a new, experimental psychiatric drug, professional guinea pigs would see it as presenting the highest risk, something to be avoided if possible because it “it messes up your mind.” Still, mindful of these obstacles, the pharmaceutical industry offers the highest payment for these types of trials in an attempt to recruit reluctant trial subjects. Almost everybody I encountered during my fieldwork admitted that, despite their concerns, they had done at least one trial they thought was too risky, enticed by the $5000 to $10000 financial reward. The industry is very aware of the role financial compensation plays in recruiting and controlling volunteers and they use it strategically to ensure compliance. Furthermore, the industry has outsourced the daily operation of the trials to Contract Research Organizations (CROs) that recruit the volunteers, carry out the trial and then hand the data to the industry. Since Phase I trials involve a small number of volunteers, between 20 and 100, if only one or two drop out in the middle of the trial, it compromises the validity of the whole trial. To avoid this, the CRO’s use professional subjects that know what to expect from the trial when possible and they also use money to make sure subjects stay in the trial until the end. If a subject drops out in the middle of the trial they get a prorated amount. But

the bulk of the payment is scheduled at the end, usually followed by a bonus for completion to encourage participants to stay until the end, no matter what. I have argued that this practice is unethical and challenges current ethical arrangements regarding the participation of human subjects in research. My main concern however is that the market recruitment of trial subjects might place trial subjects in danger, not only because of the risks they face in particular trials, but also because they receive a high dose of chemicals during their years of trial participation that might interact many years later with each other, with drugs taken by the patient as part of a treatment, or with toxic pollutants in the environment. I have suggested the creation of a centralized registry of phase I participants to avoid their participation in more than one trial at a time, or without waiting the mandatory 30 day wash-out period after a trial ends. This registry would protect subjects but would also enhance the validity of trial findings that might now be confounded by the undetected presence of participants volunteering surreptitiously in other trials.

Currently I am extending my research beyond the group of mostly male, white professional guinea pigs that was the focus of *The Professional Guinea Pig*. As mentioned, most professional trial subjects testing drug safety in America are from a different background, often from poorer minority groups. Most trials in Philadelphia run without any professional guinea pig like the ones described in my book. In some trials there might be one, or two. They are only a tiny minority. They are important because their degree of organization and because public guinea pig culture gives visibility and voice to all, and because their interests and experiences are similar to other professional guinea pigs. Still, journalists have reported extreme cases of abuse and exploitation of minority guinea pigs that make me think that more research looking into these minority professional guinea pigs is needed. For example, poor and homeless African –American males, some with drug or alcohol-related problems have been recruited into trials in the mid-west. And undocumented Latinos have been recruited in Miami, Florida. In a paradoxical turn, a facility in Neptune, New Jersey enrolls mostly African-American ex-cons for their trials, recruiting them as they walk out of jail. My present research focuses on these groups trying to identify how race and class shape the participants' experiences of the trial. African-Americans for example have been very wary of biomedical research – and for good reason after Tuskegee. I want to understand how these participants overcome their fears in order to participate, the risks they might face and the effects financial rewards play in their decision to join the trials. These are extreme cases of abuse and exploitation in clinical trials research, but they call attention to the participation of minorities in testing drug safety thereby alerting us to the interplay of race and class in Phase I Trials research.

Finally, there is a development, brought about by the increasing use of

financial compensation during all the phases of Clinical Trials research, that I find, very, very troubling. Talking with a source that manages a CRO recruiting for Clinical Trials Phases II and III, he told me that he had learned that poor minority HIV patients often enroll in two trials at the same time, seeking to maximize financial gain. These trials involve hundreds or thousands of participants and last many years. They do not pay the large amounts Phase I trials command because in the first case it is assumed that since subjects are healthy they will not have any other interest in doing them but money. These trials might pay only a few dollars every month, sometimes $20, $30 or so, to encourage participation. Still, for poor patients this meager reward seems to be inducing them to do two trials at the same time. This is of course, illegal, and unethical. These patients, like elderly patients trying to supplement their pensions with trial income – as was recently reported in a major newspaper-, are often sick and ailing from serious conditions. Their trial, designed not to treat them but to answer a scientific question about a drug or drug regime, is instead, making them sick. And it concerns me that, as like in the case of professional guinea pigs doing Phase I Trials, there is no centralized registry of their participation either. My research is not only an ethnographic exploration into the realities of clinical trials research in America, it is also a "call to action." We have to stop the neoliberal deregulatory folly and start to carefully build regulatory frameworks to better protect trial subjects and consumers. Why not advance the idea of a centralized registry for all clinical trial participants in the US?

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