



## What if Institutional Review Boards (IRBs) treated healthy volunteers in clinical trials as their clients?

Martin Tolich

Sociology, University of Otago

---

### RESEARCH

---

Please cite this paper as: Tolich, M. What if Institutional Research Boards (IRBs) treated healthy volunteers in clinical trials as their clients? AMJ 2010, 3, 12, 767-771. Doi 10.4066/AMJ.2010.431

---

#### Corresponding Author:

Martin Tolich

University of Otago, PO Box 56, Dunedin

[martin.tolich@otago.ac.nz](mailto:martin.tolich@otago.ac.nz)

[martin.tolich@otago.ac.nz](mailto:martin.tolich@otago.ac.nz)

---

### Abstract

---

**Objectives:** To understand the motivations of university students volunteering for clinical trials in New Zealand and their comprehension of risk.

**Methods:** An ethnography using both direct observation and unstructured interviews of student volunteers in two New Zealand clinical trial companies.

**Subjects:** Eighteen volunteers who participated in one of three separate clinical trials were interviewed. Thirteen of the eighteen trialists had been involved in previous clinical trials.

**Results:** 1) These university students share similarities with economically disadvantaged minorities – they do not actively engage with the informed consent process, and they arrive at the trial ready to consent. 2) Word of mouth endorsements from incumbent trialists are the main factor influencing students' decision-making process. 3) The trialists' assessment of harm focused more on the working conditions (i.e. the food they were required to ingest) than on the research drug.

**Discussion:** Economic disadvantage is not a necessary precondition for volunteers to arrive at a clinical trial ready to consent. These university students were motivated to consent via informal networks sharing information about these lucrative trials. Trialists' definition of harm may be broader than that of ethics committees. Ethics committees could employ a post-study questionnaire to evaluate healthy volunteers' experience of the trial.

---

### Key Words

Informed consent, healthy volunteers, clinical trials, university students, IRBs, autonomy

---

### Background

Research subjects enrolled in first-in-human clinical trials are disproportionately poor<sup>1, 2, 3</sup> – their deprived circumstances diminishing their autonomy<sup>4</sup> to the point that Elliott<sup>5</sup> characterises phase one trialists as an exploited underclass, operating within a shadow economy that bears the burden of the safety testing of new drugs<sup>6</sup>. He pejoratively refers to them as guinea pigs. Money plays an important role in the recruitment of healthy volunteers into phase one trials and it can be assumed money is likely to motivate less well off persons<sup>1</sup>. Typically, these volunteers are male, unemployed, self-employed, or working in contract jobs for finite periods, and are not primary caregivers of family members<sup>7</sup>. Fisher classifies these men as exploited, without options, and taken advantage of by clinical trial companies. "Everyone pretends that guinea pigging is not really a job" but there is no doubt that first-in-human clinical research is a business<sup>6</sup>.

Fisher<sup>8</sup>, a sociologist, dismisses the bioethical assumption that individual autonomy is present in the informed consent process. She says informed consent should not be seen as a panacea and claims economic disenfranchisement robs these men of the genuine autonomy needed to take an active role in consent. Disenfranchisement means these men are indiscriminate with risk, "not concerned about the details of particular trials in which they enrol<sup>7</sup>". They are ready to consent<sup>8</sup> and are likely to have decided to take part in the trial before participating in any informed consent process.

The healthy volunteers involved in two New Zealand companies who conduct clinical trials have a similar consent experience, yet they are not poor disadvantaged minorities. The collective sentiment of these university students was "I want the money, I don't need the money"; they participated in bioequivalency and first-in-human trials not to earn a subsistence wage but to purchase extras—a motorbike, a camera, a surfboard, a holiday to Nepal. Money was, however, a major



inducement to their participation. Additionally, this ethnography gave participants an opportunity to describe the novel ways they experienced risk, not so much from the drug, but from the food the trial company required them to ingest.

### Methods and Setting

This ethnography on the clinical trialists' experience was conducted in late 2008, in two New Zealand clinical trial companies (First Company and Second Company) located in different cities. Both companies are situated near a hospital and had an abundant ready to recruit labour supply from a regional university. First Company ran only bioequivalency trials and was used in this study as a pilot for Second Company that ran both bioequivalency trials and first-in-human trials. In all, 18 persons – who participated in one of three separate trials – were interviewed. One trial was a bioequivalency trial in First Company (N=7) and two trials were in Second Company including one bioequivalency trial (N=6) and one first-in-human trial (N=5) of a new drug.

All but one of the 18 trialists was enrolled in tertiary education with an age range from 19 to 22. The outlier, a fifth-time trialist, a tradesman, was aged 34. Thirteen of the eighteen trialists had been involved in previous trials and were able to provide information on other trials ranging from relaxed “bleed and feed” trials to intensive taste alteration trials.

The main difference between the two companies was the remuneration and duration of the trial. Participants in First Company's bioequivalency study were paid less than Second Company. First Company paid nine hundred dollars (AUS 689) total for two consecutive weekends. The amount of money was before tax, with no hourly rate advertised. When recalculated as an hourly rate for the two 36 hour residencies, First Company's hourly rate was \$12.50 (AUS 9.58), equating to New Zealand's minimum wage.

Second Company's residencies for both its bioequivalency and first-in-human trials were 63 hours in duration compared to First Company's 36 hours. The payments to participants in the Second Company trials were significantly greater than payments by First Company. Second Company's trialists' hourly rate for their bioequivalency study was \$16.66 (AUS 12.76) per hour or bulk funded at \$4,200 (AUS 3218) for the four residences over consecutive weekends. Those taking part in the one-off 63 hour first-in-human trial were paid more, a flat rate of \$2500 (AUS 1916). Their hourly rate was \$39.68 (AUS 30.40).

### Ethics

Ethics approval for this non-biomedical research was gained from the University of Otago Human Ethics Committee, prior to each stage of the research in First Company and Second Company.

### Results

I observed each of First Company's two residential sessions (held over consecutive weekends) for over one hour. Seven of

these twenty-four participants (four female and three male) were subsequently interviewed, their comments later transcribed and thematically coded (N=7). During these interviews a labour market metaphor solidified as a useful representation for the ways the trialists described their recruitment into the trials. Trialists said that their friends had recruited them into the trial by sharing access to good money. The colloquial New Zealand expression is “jobs for the boys.”

*A friend said “You want some quick cash? Easiest way.” I think that's what everybody says. You know, so yeah, he said apply, but just read what you're doing first. They're very good. They give you everything you need to know, and so you read about it and it's pretty simple.*

The informal recruitment narratives raised by First Company participants were similar to the stories Second Company trialists told me. Entry into the trial was reliant on inside information obtained via friends.

*A few of my friends have done one and they told me it was fine and well worth what they got back.*

*Um, I had a friend who'd done one in [another town] and he told me about it and then I happened to see an advertisement for this and we did one together.*

The *in crowd* – those students privy to knowledge of the lucrative trials – were complicit in the recruitment of new trialists. As labour market insiders, they let their friends in, not wanting to broadcast the trials openly for fear a huge influx of new volunteers would restrict their future access.

*I've got to stop giving out information on it, 'cause there'll be too many people trying, yeah, everybody seems quite keen to.*

Word of mouth recommendations vouched for the safety of the trials and described the bloods protocol down to the formal informed consent process presented by the clinical trial company. A first-timer in the trial explains how he was informed about some, but not all the details:

*This was the first one I'd ever done. If I hadn't have had friends that sort of explained it to me it would have been a bit like, “what's going on here”. Because they sat me down and said they do this and that, “you sit there with a line [cannula] in for the day”. So I kinda knew more or less what to expect. But when you get there and you see all those [glass] vials at the foot of your bed and you're like, I got to fill all those (giggles).*

In the UK, clinical trial companies<sup>9</sup> offer between ninety to three hundred and fifty pounds for any incumbent trialist to recommend a friend to the clinical trials company. In New Zealand this referral is gratis, although it may have non-financial repercussions. If trialists arrive at the trial



informed by friends about the remuneration and the trial procedures, the informed consent process becomes a ceremonial exchange rather than a robust process. There is no blame apportioned to either company here, nor is this finding new. Dixon-Woods et al.<sup>10,11</sup> found volunteers only made limited use of the written information. Morris and Schneider<sup>12</sup> concur, assuming IRBs take for granted that research volunteers took a passive role in the consent process. Second Company trialists were no different, freely admitting they were not active readers of the information sheets. Trialists saw the consent process as a rite of passage but they believed the company was not active either.

*I don't think that they go out of their way. I don't think they try particularly hard to make sure that we fully understand the drug we're taking at all, mostly because a lot of the patients here aren't really, don't care so much, you know, they'll wanna know a little bit about it but not really in-depth. Knowing basically what it is and what it's doing but generally if, yeah, I mean you can do your own, they're, they're very willing to answer questions.*

The management of self to be a good trialist was practised during the trial when trialists rigorously subjected themselves to the scientific protocol in order to ensure future employment.

*If you're a good volunteer, you're going to be on the computer, you know, a great volunteer. Always good. But if you do something wrong you get a bit a black mark against you or something like that, you might not get asked back.*

A Second Company participant said he was a good trialist between trials. He purposively avoided high-risk activities that may require prescription drugs prohibited in clinical trials.

*I look after myself on the outside as well, things I might normally do I might not, because if I broke my leg or something and I had to have some kind of pain killer or something it could mean that I couldn't, I'd have to discontinue. So, yeah, just for that.*

In both companies the formal consent process was preceded by an informal recruitment and consent process within an informal labour market<sup>13</sup>. Friends recruited friends via word of mouth, endorsing the safety of the trials. Thus, these healthy volunteers share a similarity with the minority men who Fisher<sup>7</sup> discusses, as they too are 'ready to consent' when they arrive at the informed consent process. The absence of economic vulnerability and exploitation in these volunteers allows us to extend Fisher's<sup>7</sup> "ready to recruit, ready to consent" analysis. Although the 18 volunteers are not indiscriminate with risk (as are the disenfranchised men) their experience of risk during the trial has not been taken into consideration. Thus an element of genuine autonomy is diminished through-out the trials. These volunteers are as much service sector employees and university students, as they are research subjects. IRBs could be more effective if they tapped into the volunteers' insights about how harm is

experienced in clinical trials. A post trial evaluation, as described below, could provide additional information about perceptions of harm.

#### *Food as Risk or Harm*

First and Second Company trialists put up with a great deal without complaint because as a rule research subjects do not complain, not wanting a black mark put on their computer file. Nor is there an outlet for complaints. These healthy volunteers were needed, prodded, bled and monitored. In these three trials, however, concern about food was the main complaint. Second Company trialists had no problems with the quality of the meals but complained resolutely about the absence of snacks.

*You [laughs], you count down the minutes to your meals, 'cause that's the pretty exciting part of the day [laugh]. You've got your three set meals but we're all used to having a few snacks and that. So it sort of plays on your mind late at night. You get the munchies and start craving food.*

The irony for First Company trialists was that they saw little risk in taking the drug – their risk was being required to eat the breakfast not once, but twice. The seven First Company trialists agreed the worst part of the trial was the nausea, induced by a high fat diet (as the information sheet described it). How they ingested the food, rather than the drug, was the issue.

*You had to eat all this breakfast and it was horrible. The eggs were like plastic. There was a muffin that you had to eat, it was errr, solid and the bacon was half cooked, and you had to drink a glass of milk and a glass of water and it was so bad. It was the worse part of the trial for me. The second time was worse 'cause I knew what was for breakfast coming, you knew it was going to be horrible and it was.*

*Not the best thing to have at 7.30 in the morning.*

*The food's not that great. It's worse than Hall food (sniggers)*

In this study food was the issue – in other trials it may be hard beds, the absence of privacy, the surly staff or a rogue staff member. Table 1 pg 771 provides an anonymous end-of-trial assessment that would capture, as yet unrecorded information about the everyday experience of men and women who participate in clinical trials. Scoring of this questionnaire is standardised as a satisfactory result (strongly agree 1, agree 2) would have subjects score the clinical trial company with a low cumulative score. Higher scores (strongly disagree 4) would be a cause for concern for an IRB, requiring the trial company to explain their high score and how they



planned to rectify it in future studies.

## Discussion

These university students are not a disenfranchised minority nor are they paid to give word of mouth endorsements to their friends. Their motivation to take part in trials is driven by money, not out of need, but the desire to purchase luxury items such as a holiday, a motorbike, a new camera. The word of mouth endorsements make this group ready to consent when they arrive to take part in the clinical trial companies' consent process. Ethics committees could require Second Company to lower its payments to trialists but this is unlikely to curtail involvement as the First Company trialists already sign up in three times the number required, and are willing to work for half the money. Singer and Couper<sup>14</sup> also found that "larger financial incentives do not induce research participants to accept higher risks than they would be unwilling to undertake with smaller ones."

In many ways, these New Zealand trialists are like seasonal horticulture workers who accept any job that fits their schedule. New Zealand seasonal workers know picking summer cherries is more lucrative than thinning grapevines in the winter. These Second Company trialists do not negotiate their rate of pay; they accept that bioequivalency and first-in-human trials pay different rates, but any money that pays students for sleeping or studying, and is paid for short periods (three of four times a year), is good money.

Ready to consent disenfranchised economic groups and university students recruited via word of mouth both undermine the informed consent process, supposedly the cornerstone of the ethics review system. IRBs can, and should, do more for research subjects in clinical trials to protect them from harm during a trial – in particular, by assessing *their* perception of harm

A post-trial evaluation appraising the research subject's experience of the clinical trial allows the research subject to assess various moments of the trial and anonymously share that information with the ethics committee. The evaluation would include questions such as: How successful were the trial company at explaining the trial protocol to subjects? Did the trial proceed as outlined in the information sheet? What aspects of the trial, if any, were unexpected? How does the research subject evaluate their experience on the trial, and would they do another trial with this company if an opportunity arose? This type of evaluation is not novel, and is incorporated by other service sector employers (hotels, supermarkets, airlines) who co-opt their clients to evaluate customer service<sup>15</sup>. Moreover, university students routinely evaluate their courses in a numeric questionnaire, appraising the subject matter and textbooks, the teaching and support staff, and are also invited to comment in their own words. These evaluations do not relieve problems experienced in their course but they ameliorate similar problems in future courses. In the same way, a general end-of-trial assessment would reduce the likelihood of problems in future clinical trials that many of the volunteers are likely to participate in.

They should be treated with respect and accorded the status of clients, not 'guinea pigs'.

---

## References

1. Iltis, A. (2009). Payments to Normal Healthy Volunteers in Phase 1 Trials: Avoiding Undue Influence While Distributing Fairly the Burdens of Research Participation. *J Med Philos* 34(1), 68.
2. Dresser, R. (2009). First-in-Human Trial Participants: Not a Vulnerable Population, but Vulnerable Nonetheless. *J Law Med Ethics* 37(1), 38-50.
3. Dunn, L., & Gordon, N. (2005). Improving informed consent and enhancing recruitment for research by understanding economic behavior. *JAMA*, 293(5), 609.
4. Cooper, M. (2008). Experimental Labour—Offshoring Clinical Trials to China. *EASTS*, 2(1), 73-92.
5. Elliott, C. (2008). Guinea-Pigging: healthy human subjects for drug-safety trials are in demand. But is it a living? *New Yorker*, January 7, 2008.
6. Elliott, C., & Abadie, R. (2008). Exploiting a research underclass in phase 1 clinical trials. *N Engl J Med* 358(22), 2316-2317.
7. Fisher, J. (2008). *Medical research for hire: The political economy of pharmaceutical clinical trials*: Rutgers University Press
8. Fisher, J. (2007). "Ready-to-Recruit" or "Ready-to-Consent" Populations? Informed Consent and the Limits of Subject Autonomy. *Qualitative Inquiry*, 13(6), 875.
9. (<http://www.trials4us.co.uk/> Sourced July 3, 10)
10. Dixon-Woods, M., Ashcroft, R., Jackson, C., Tobin, M., Kivits, J., Burton, P., et al. (2007). Beyond. *Soc Sci Med* 65(11), 2212-2222.
11. Cox, A., Fallowfield, L., & Jenkins, V. (2006). Communication and informed consent in phase 1 trials: a review of the literature. *Support Care Cancer*, 14(4), 303-309.
12. Morris, N., & Schneider, M. (2009). Volunteer research subjects' experience of participation in research on a novel diagnostic technology for breast cancer. *Qual Health Res*
13. Doeringer, P. Piore, M. (1971) *Internal Labor Markets and Manpower Analysis*. Massachusetts. D.C Heath and Company.
14. Singer, E., Couper, M., Bentley, J., & Thacker, P. (2008). Do incentives exert undue influence on survey participation? Experimental evidence. *Journal of Empirical Research on Human Research Ethics*, 3(3), 49-56.
15. Tolich, M. (1996) Public Control: Making the Customer a Supervisor in the Fordist Service Sector" *New Zealand Journal of Sociology* 11:1: 66-88



**ACKNOWLEDGEMENTS**

I thank the peer reviewers of this article.

**PEER REVIEW**

Not commissioned. Externally peer reviewed.

**CONFLICTS OF INTEREST**

The author declares that he has no competing interests.

**FUNDING**

The research was funded by a University of Otago Research Grant.

**Table 1: Evaluating Healthy Volunteers' Experience of Clinical Trials**

Please respond to the following statements by ticking the box on the strongly agree to strongly disagree scale. When you are finished put the survey in the self-addressed envelope provided. This information will monitor this clinical trial and enhance the experience of healthy volunteers' in future clinical trials. The ethics committee collating the responses will treat them as anonymous.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. The Clinical Trial was well organised.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. The Clinical Trial Company informed me about the risks of taking part.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. The money I received from taking part in this clinical trial was sufficient.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The quality of the food was excellent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. The quantity of the food was sufficient.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The Clinical Trial Company made me aware of the adverse effects of this drug.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. The Clinical Trial Company made me familiar with the insurance cover of the trial.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. The duties required of me in the Clinical Trial were reasonable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The Clinical Trial Company staff treated me with respect.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. If given the opportunity to participate in another trial run by this company I would take part.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In your own words, describe how your experience of taking part in the clinical trial could be improved.

Thank you for sharing your experiences of taking part in the clinical trial. Please put the completed survey in the self-addressed envelope supplied.