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Research Participation as Work: Comparing the Perspectives of Researchers and Economically Marginalized Populations

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Abstract

We examined the historical and regulatory framework of research with human participants in the United States, and described some possible unintended consequences of this framework in the context of paying young injection drug users for their time participating in behavioral and medical research. We drew upon our own experiences while conducting a long-running epidemiological study of hepatitis C virus infection.

We found that existing ethical and regulatory framings of research participation may lead to injustices from the perspectives of research participants.

We propose considering research participation as a specialized form of work and the use of community advisory boards to facilitate discussion about appropriate compensation for research participation among economically marginalized populations.

As Researchers, Our Constructions of what is and what is not "ethical research" have been heavily informed by our knowledge of the terrible ethical failures of members of our tribe within the past 70 years—the willing participation of some scientists in human experimentation on the victims of the Holocaust, the Tuskegee experiment, Willowbrook, the Milgram experiments, and numerous other large and small abuses of human beings. Responses to these horrors, such as the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, and their derivative processes, protocols, and laws have all sought to describe and codify what comprises ethical research, and in doing so prevent future abuses. In the United States, the most important of these has been the 1979 Belmont Report, a product of the then–US Department of Health, Education, and Welfare. The Belmont Report enshrines 3 principles for research: respect for persons (protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent), beneficence (maximizing benefits for the research project while minimizing risks to the

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Human Participant Protection: All study protocols and procedures were reviewed and approved by the UCSF institutional review board. Ethnographic observation and qualitative interviews were carried out under UCSF institutional review board approval numbers H9973-16833-8, H9973-16833-9, and H9973-16833-10.

research participants), and justice (ensuring reasonable, nonexploitative, and well-considered procedures are administered fairly).[1] The policy approach described in the Belmont Report is largely implemented in US law through Title 45 (Public Welfare), Part 46 (Protection of Human Subjects) of the US Code of Federal Regulations (hereafter 45 CFR 46), which provides minimum standards required for federally funded research involving human participants.

Taken as a whole, 45 CFR 46 and the history behind it create what the sociologist Erving Goffman referred to as a "frame," a way of ordering and making sense of a situation that has consequences for how we understand subsequent events.[2] A simple example of how framing can have a significant impact on the way an individual understands an event can be seen in a common medical procedure such as a testicular or cervical examination: a relative stranger asks the individual to disrobe, then views and even handles the individual's genitals. Under almost any other circumstance, this would be experienced as a violating and even traumatic event because the individual would understand the process as an assault. However, because the event happens within a framework shared by both participants, one that locates the medical practitioner as someone acting in the best interests of the individual's health, and the individual as someone who has sought out the examination for the benefit of his or her health, such an examination is rarely more than mildly discomforting. In the case of 45 CFR 46, the code likewise contains a number of elements that together act to create a frame that shapes how researchers and institutional review boards (IRBs) interpret and understand situations that arise in the course of research involving human participants.

We describe possible unintended consequences of this framework in the context of conducting research with young, economically marginal users of illicit drugs. This article is drawn from our experience conducting research with young injection drug users in San Francisco over a 12-year period.

Setting and Approach

The "UFO Study" ("U Find Out") is a National Institutes of Health–funded study of hepatitis C virus (HCV) infection and other health outcomes among young injection drug users conducted at the University of California, San Francisco (UCSF). The study has been in almost continuous operation since 1997, and has followed some participants longitudinally since 2000. In almost all respects, the UFO Study is a standard prospective observational epidemiological study: it conducts rigorous, thoughtfully designed research out of community-based field sites using well-documented protocols and exceptionally well-trained staff. It is slightly unusual in that field sites are modeled on "youth drop-in" services operated by community-based organizations, and, as such, provides services and a community space to young injection drug users and their peers regardless of whether they are current study participants. The walk-in field sites provide access to food, basic medical care, injection supplies, referral to other social services, and simply space to be out of the weather in a non-judgmental environment. Study staff have almost universally had previous employment at social service agencies serving young injection drug users, and regard service delivery as a key component of their job. Because of the presence of these additional resources, many study participants spend time at UFO Study field sites on days for nonresearch purposes.

To be enrolled in the study, potential participants must be aged younger than 30 years and have injected at least 1 illicit substance in the 30 days before enrollment and be HCV-negative at entry.[3,4] Participants are almost universally homeless, are generally highly "visible" in street settings, and are highly stigmatized and economically marginalized. A third have been incarcerated for 1 or more days within the past 3 months.[5] Their main

sources of income are panhandling (begging), selling drugs, sex work, and petty theft such as shoplifting.[6]

The first author (P. D.) worked for the UFO Study between 2000 and 2009, and was the project director from 2002. Between 2003 and 2009, he was also a doctoral student in UCSF's medical sociology program, and conducted qualitative interviews and ethnographic observation with UFO Study participants from 2007 to 2009 in relation to dissertation research. Fulfilling these multiple roles entailed spending somewhere in the vicinity of 2000 hours working at study field sites, and conducting enrollment activities including informed consent for more than 300 participants. In addition, as project director, the first author was responsible for drafting applications and renewals for IRB approval for the study. The second author (K. P.) has been principal investigator of the study since 2002, and was a coinvestigator from its inception in 1997.

This article is a product of these experiences, in that it grew out of a sense that the ways the young injection drug users talked about their participation in the study were sometimes at odds with the ways IRBs frame and understand research participation, and that this apparent disjunct was worthy of further attention. To illustrate this apparent disjunct, we use a handful of quotes and comments made by UFO Study participants, drawn from field notes and transcripts collected as part of the first author's dissertation fieldwork. It should be noted, however, that ethical issues were not the focus of that project, and the quotes given are intended to illustrate a point rather than be representative of a body of data. All UFO Study protocols and procedures were reviewed and approved by the UCSFIRB. Ethnographic observation and qualitative interviews were carried out under UCSF IRB approval numbers H9973-16833–8, H9973-16833–9, and H9973-16833–10.

The Ethics of Paying Research Participants

In the United States, biomedical and behavioral research with illicit drug users almost universally involves paying study participants. We use the term “payment” rather than “reimbursement” throughout this article to focus on the fact that money is changing hands, rather than on the perceived purpose of the payment.

There is a substantial existing literature on ethical issues surrounding the payment of impoverished and vulnerable populations,[7–10] including specific literature on concerns around cash payment of active injection drug users.[11–13] The principal ethical concerns of this literature are that payment of economically marginal individuals could constitute undue inducement and hence undermine the principle of voluntary participation; or that study participants might use the cash they are paid to purchase drugs—in a putative worst-case scenario, a participant's fatal drug overdose might be funded by research money. A further concern is that payment may lead to inaccurate study results through, for example, unrepresentative sampling (by overrepresenting economically marginalized individuals) or by biasing response (as participants may alter their responses to questions if they believe ongoing participation depends on particular responses). In either case, inaccurate research outcomes may lead to policies or interventions that do not benefit the population as intended.

Although we appreciate the dilemmas associated with making cash payments to active drug users (having handed out tens of thousands of dollars over the past decade, and having more than once seen the same individuals clearly under the influence of drugs shortly after, or having seen a potential participant go from complete lack of interest to immediate assent upon discovering that they would be paid to do something), we suggest that examining how research participants view payment might be fruitful.

Participant Understandings of Payments and the World of Work

One of the key ways participants have described their participation in the UFO Study has been as a source of income. In response to a survey question asked quantitatively of participants "In the last 30 days, what were all your sources of income?," some have included in their answer, among many other income-generating strategies, "participating in paid research studies." Some carefully arrange their participation in different studies being conducted by different institutions in a systematic attempt to ensure that they will "get paid for *something* every week." More casually (and perhaps worryingly), some assent to specific procedures on the discovery that they will be paid.

In the broader biomedical research field, there are other sources of evidence for the idea that research participants often regard research participation through the lens of paid work. As an example, *Guinea Pig Zero*, "an occupational jobzine for people who are used as medical or pharmaceutical research subjects" discusses topics such as unionizing research participants, provides "report cards" on the "conditions of work" prevalent at specific research facilities and long-running studies, and even contains stories on successful research participant agitation for "better pay" for participation in specific studies.[14,15]

From another direction, recent documents produced in Canada in consultation with drug user groups have emphasized the need to involve active drug users at all levels of public health policy and intervention design, explicitly reframing such participation as, at a minimum, "expert consultation."[1] (p28) As expert consultants, payment becomes a norm rather than an exception. In a list of "dos and don'ts" for consulting with people who use drugs, we find: "Do provide an honorarium—contrary to most people who attend your meetings, we are not paid to attend by our jobs, but still need to look after our needs."[1] (p37) From this perspective, a drug user who participates in epidemiological research that includes survey-based behavioral or exposure questions, such as the UFO Study, is sharing his or her expertise—parsing his or her experiences in ways that respond appropriately to quantitative questions or leading an interviewer through the complexities of his or her experiences in a qualitative interview, rather than simply sharing his or her time or volunteering a type of "use" of his or her body.

Risk, Being "Ripped Off," and Undue Inducement

In some detail, 45 CFR 46 describes the required elements of informed consent, including the requirement that the consent process include a description of foreseeable risks associated with participation. In studies such as the UFO Study, these risks are predominantly nonphysical, and relate to issues such as the potential for psychological distress, loss of confidentiality, and loss of privacy.

Privacy and confidentiality are not unimportant to UFO Study participants; however, as noted by the anthropologist Philippe Bourgois in his work in San Francisco, a far more pressing concern of homeless, unemployed, and socially marginalized injection drug users in their interactions with potential sources of income is "Am I going to get ripped off?"[17] In short, a primary concern is that the time and effort spent traveling to a study field site, waiting to be screened, and participating in study-related activities may not be reimbursed as expected. The more complex a given study, the greater the chance a participant may, at some point, feel "screwed" by that study, even one staffed by highly skilled and subculturally aware field staff. The National Institutes of Health training guide for human research ethics (which provides the material for most required training programs) has approximately 6 pages (out of 73) devoted to the protection of privacy and confidentiality; by contrast, it has nothing at all on how to go about paying research participants in ways that protect them from injustice, accidental or otherwise.[18] Likewise, 45 CFR 46 contains no

direct mention of the payment of human participants (beyond payment for injury sustained by participation), and the only element of the code usually interpreted as bearing to payment is the requirement that prospective participants not be subject to “undue inducement.”

In practice, however, the question of what constitutes “undue inducement” is considerably complicated by the widely varying economic circumstances of individual participants, even within a study of predominantly homeless injection drug users. As an example from our study, a young man, describing his initial contact with the UFO Study some years afterward, told the first author, “It was amazing—you gave me *20 bucks* just for getting a test. That was more money than I'd had in my hands at one time in ages!” Measured against this young man's “normal” economic situation, he clearly saw $20 as a significant amount of money. As a consequence, it is hard not to see $20 in this context as possibly constituting “undue inducement.” By contrast, during a quantitative interview with another young man whose main form of income was sex work, the interview was repeatedly interrupted by his pager going off. Each time the pager went off, indicating that a prospective client was trying to contact him, he'd remark “There's another hundred bucks gone,” occasionally adding for emphasis “How much am I getting for this [interview] again?” (in this case, $10). Just as clearly, measured against this man's normal economic situation, it is much harder to see the $10 in question as “undue inducement” (putting aside for a minute the issue of whether [or, rather, how] this person was using the fact of his pager going off to represent himself as “doing well,” and whether this representation of his economic success might have been exaggerated).

Although the informed consent process usually addresses the absolute basics of payment, in that they list the mode (cash or otherwise) and schedule for payments, they cannot and do not functionally address these concerns, because their fundamental starting point is the framing that “research is voluntary.” This framing acts to prejudge payment as potential undue inducement, and largely limits IRBs to considering whether a proposed payment does or does not meet some set of criteria for undue inducement, rather than whether the payment is “just” from the perspective of economically marginal participants. Fundamentally, the problem is that “research participation” is a classificatory label for an experience that can be understood in a number of ways. Acts that would be “labor” or “work” in other contexts are framed exclusively as “voluntary altruistic participation” in this one. However, as shown previously, we suggest that economically marginal drug users often, if not exclusively, understand time spent answering research questions as “work,” and frustrations they sometimes express with participating in research often stem from this disjunctive classification. The Belmont Report explicitly identified “justice” as 1 of the 3 essential components of ethical research. From the point of view of researchers used to framing their research in terms of the Belmont Report and subsequent regulation, “justice” refers to the fair distribution of the burdens and benefits of research. From the perspective of a UFO Study participant, however, being compensated appropriately for his or her effort *is* justice; having effort disconnected from payment has the potential to produce a sense of being “ripped off”—of producing injustice in the broader sense of the term.

Possible Alternatives

If we look at research participation for a moment as a specialized type of paid employment, then the relationship of the 2 individuals described previously to the payment they received looks quite different. For example, if the person talking about how great it was that he would be paid $20 had been describing an hour's work helping someone move furniture, few if any listeners would have had ethical concerns-even though the money could be construed as an “inducement” to do something he probably would not have done without the inducement.

We suggest that it may be a useful exercise to consider proposed research protocols through both the existing framing of research participation as a voluntary activity *and* through the framing of research participation as a specialized form of work. Elements of protocols that may look entirely ethical (or ethically troublesome) in one frame may be cast in a new light from the perspective of the other, with improved outcomes. The "world of work" has ethically and socially grounded protections that act to minimize extreme abuses of power and circumstance— something also central to the task of IRBs. For example, the rights of employees to litigate against their employers are much greater than those of research participants, whose scope for redress is usually limited to medical treatment of injury demonstrably caused by participation,[19] and IRB approval and appropriate informed consent are substantial protections against malpractice and negligence, respectively, in US case law.[20] Furthermore, in the United States, scope for redress does not include such workplace accident basics as compensation for loss of future income because of their injury (unlike many European countries, where mandated insurance coverage for research participants is common[21]). The multiplicity of agencies and institutions with active voices in the regulation of worker—employer relationships is far broader than those currently present in the regulation of research conduct.

Second, even if incorporating some of the protections of the workplace into the world of research participation is not possible, we argue at a minimum for the inclusion of individuals from the population from which research participants will be drawn in discussions about how, when, and how much to pay participants in proposed research. One encouraging development in recent years has been the increasing use by researchers of community advisory boards (CABs) to inform and advise research questions, design, and implementation.[22–24] The CABs have excellent potential as a workaround for problems of representation and top-down approval processes, but require that the researchers choose to submit themselves to such processes and commit to honoring outcomes of CAB deliberations. There is currently no requirement in the United States that researchers working with marginalized populations (or any population) utilize a CAB, nor are there well-established guidelines for choosing CAB members or structuring CAB processes to ensure representativeness and responsiveness. Although we are not suggesting that CABs be mandated for all research projects, we suggest that further work to formalize the use and makeup of CABs may be of considerable value.

Finally, 45 CFR 46 already suggests (and in the case of prisoners requires) that members of study populations or those with the ability to speak on their behalf be included in IRB deliberations, and we suggest that there is room for this practice to be regularly utilized for research involving economically marginalized populations.

Conclusions

The moral philosopher Arne Vetlesen has argued that ethics is in its essence the apprehension of something as a moral problem.[25] To suggest that we think of research participation as "work" is not to disown the ethical dimensions and problems of conducting research with human participants; rather, we see it as acknowledging the immorality of providing research participants with fewer protections than they would have as formal paid employees.

Voluntary consent may be enough if all we wish to do is prevent another Tuskegee or Willowbrook; however, at the heart of those failures was an indifference to the role of research participants as human participants. A research model that frames participants as expert consultants shifts the bar; it locates "the researcher" as simply one of the expert voices in the room. In a society in which social value and hierarchy are often linked to pay,

recognition of participants as paid expert consultants may be better protection from the kinds of thinking that made it acceptable to the Tuskegee researchers to continue their work.

Finally, if a central element of ethical research is “justice,” discussions about compensation have to be open. By mandating a framing that locates payments as potential undue inducement, 45 CFR 46 severely limits such discussions. The IRBs are required to prioritize consideration of payments in terms of meeting or not meeting some criteria of undue inducement before any consideration of payments as just or unjust. Researchers who need research approved may feel obliged to minimize payment levels to avoid potential censure, and are unable to utilize arguments from a labor framing that would locate appropriate compensation as an issue of justice, out of concern that such an argument might run foul of the “undue inducement” framing. We argue that researchers and IRBs be encouraged to consider proposed protocols through multiple lenses, and that additional mechanisms, such as the use of CABs, may allow free and appropriate discussion of the just reimbursement of study participants without requiring a wholesale replacement of current federal code and the excellent protections it already provides.

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