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Abstract

In health care, the white coat symbolizes professionalism, trustworthiness, and competence; it also represents power. This suggests that the wearing of a white coat could influence the decisions of potential subjects who are asked to participate in clinic-based research.

Comments

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*Pilot Study:
Does the White Coat Influence Research Participation?*

In health care, the white coat symbolizes professionalism, trustworthiness, and competence;^{1,2} it also represents power.³ This suggests that the wearing of a white coat could influence the decisions of potential subjects who are asked to participate in clinic-based research. Ethical standards require that subjects' decisions to participate in research be free from undue influence, however.^{4,5} Here, we report on a pilot study that examined whether subjects were more willing to participate when asked to do so by researchers who wear white coats. The opportunity to carry out this study arose in the context of other research we were conducting regarding informed consent.

We performed a randomized controlled trial of alternative forms of a consent form for DNA banking for research (results in preparation). Subjects were recruited in the clinical apheresis unit and the General Clinical Research Center (GCRC) at the Hospital of the University of Pennsylvania. Clinic staff identified and approved patients whom we could approach and invite to participate in this study. Following such approval, one of three interviewers asked potential subjects to participate in the consent form study. Potential subjects were told that we were studying a consent form and would like them to read and complete the form as if it were real, but that no blood or medical information would be taken as part of our study. The interviewers wore casual business attire. It was recommended that our interviewers wear white coats, conforming to standards of professional decorum (as well as hygiene) in the hospital setting.

Our interviewers were authorized to be in the clinics, but they had no medical responsibilities or clinical training (nor were such necessary for our study of consent forms). But the wearing of white coats could be interpreted by patients as a sign of medical training and sta-

tus, and thus potentially affect their decisionmaking. Because it is completely unknown whether the white coat influences potential subjects' decisions, we decided to study whether the coats make a difference in willingness to participate.

This pilot study was approved by the Penn Committee on Studies Involving Human Beings. We randomly assigned days of the week on which interviewers would wear white coats, with no stratification by clinic or interviewer to ensure that the interviewers would be dressed the same if they appeared in the clinics together. Between January 1999 and March 2000, we were cleared by clinic staff to approach 370 individuals. Of these, we were able to ask 255 (69%) to participate. Others were asleep or otherwise occupied. Complete

Table 1. Summary of participant-provided demographic information	
Number of participants	206
Gender	
male	93
female	101
unknown	12
Age	
mean	46
range	18-80
Race	
White	159
African American	23
other	9
unknown	15
Education	
< high school	37
some college	55
college graduate	48
> college	53
unknown	13

data is available on 250 (98%) of those approached. Of these, 206 subjects (81%) participated. We collected demographic data only from participants (Table 1).

We examined whether wearing a white coat increased the likelihood of participation, whether individuals already involved in research in the GCRC were more likely than patients in the apheresis unit to participate, and whether there were different par-

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Table 2.
Raw participation data (participation rate) for each interviewer, by clinic in which potential subjects were solicited (General Clinical Research Center vs. the clinical apheresis unit), and by whether the interviewer was wearing a white coat (WCt)

Interviewer	GCRC		Apheresis		Totals
	NoWCt	WCt	NoWCt	WCt	
1	24/30 (.80)	27/30 (.90)	48/64 (.75)	22/30 (.73)	121/154 (.78)
2	4/5 (.80)	7/7 (1.0)	21/22 (.95)	37/42 (.88)	69/76 (.91)
3	--	--	12/16 (.75)	4/4 (1.0)	16/20 (.80)
Total	28/35 (.80)	34/37 (.92)	81/102 (.79)	63/76 (.83)	
Clinic totals	62/72 (.86)		144/178 (.81)		206/250(.82)

participation rates among the three interviewers. Participation data is presented in Table 2.

Results of logistic regressions of participation are presented in Table 3. While our data show that potential subjects appeared slightly more likely to agree to participate if the interviewer wore a white coat (85% vs. 80%), and that individuals in the GCRC were more likely to participate (85%) than patients in the apheresis unit (79%), these were not significant differences. All interactions were not significant at an $\alpha=0.05$. These results do show, however, that interviewer 2 had a significantly higher participation rate (91%) than the others (79%; $p = 0.026$). These results are confounded by the fact that the interviewer who had the high participation rate also was more likely than the other interviewers to wear a white coat ($\chi^2 = 16.4, p < 0.001$) and performed most of the interviews in the apheresis unit. We believe these were artifacts of the part-time schedules of two of the interviewers and their individual choices of clinic in which to work, both of which factors were uncontrolled in our study design.

This was a pilot study, and it was not powered to answer the white coat question; as such, we had limited power to detect effects of the size observed here. However, the relatively small odds ratio estimates of 1.2-1.5 associated with wearing a white coat imply that there is unlikely to be a large effect on potential participants' behaviors. Of course, whether any particular influence is "undue" would be difficult to determine. These results are limited to situations in which individuals in medical clinics are asked by someone not involved in their care to participate in research unrelated to their medical condition.

On one hand, we do believe that wearing a white coat would be unethical if done only in an attempt to manipulate trust for the purpose of increasing enrollment in research, regardless of magnitude of the effect. Institutional review boards should be sensitive to manipulative practices. On the other hand, if wearing white coats is otherwise justified on professional and situational grounds, the risk of modest influence suggested by our study may not be problematic. In some types of clinical

Table 3
Single and multiple factor logistic regression analyses of participation and refusal.

Factor	Simple LR			Multiple LR		
	OR	p-value	95% C.I.	OR	p-value	95% C.I.
White coat worn by interviewer	1.5	0.26	[0.76; 2.8]	1.2	0.60	[0.59; 2.4]
Interviewer 2 (vs. 1 and 3)	2.9	0.015	[1.2; 6.8]	2.8	0.026	[1.1; 6.8]
Apheresis unit (vs. GCRC)	0.67	0.29	0.32; 1.4]	0.59	0.19	[0.27; 1.3]

research (such as a clinical trial), these influences may also be simply unavoidable.

Not surprisingly, our results show that the researcher may have a marked influence on the participation decisions of potential subjects. This could reflect the perceived trustworthiness of an interviewer known to the prospective subject, which has been shown to be a strong factor in decisions to participate in clinical research.^{6,7} However, our interviewers were strangers to our subjects, suggesting that some other interpersonal factors play a role as well.

In conclusion, IRBs are charged with assuring voluntariness of participation; that is, with assuring that conditions in which potential subjects are solicited for participation and in which informed consent is secured minimize the risks of undue influence or coercion. Given the numerous possible factors that could affect participation decisions, we believe further study is needed to understand what characteristics of the researcher, the environment, the potential subject, and the interaction of these have the greatest influences on individuals' decisions to participate in research.

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