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PI or Private Investigator

Year

2001

Description

This case highlights potential dilemmas encountered by postdoctoral fellows in a research setting. Does informed consent entitle a researcher to use a credit bureau to locate study participants after three years? It also explores the ways that confidentiality might be jeopardized.

Body

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Part 1

Bob, a study manager for a health study conducted two or three years ago, needs to locate participants to follow up on some incomplete data. At the outset of the study, the researchers obtained the subjects' informed consent. In the consent process, subjects were informed of the reason for the study, told that they would be asked to complete two questionnaires, and informed of the benefits and risks of participating and their rights as study subjects. The initial consent form included a statement that mentioned the possibility of re-contact in the future. However, it provided no

information about how the contact, if necessary, would be made. At the end of a questionnaire, subjects were asked to provide the name, address and phone number of a friend or relative who would know how to contact them two or three years later. Some of the participants did not give this information.

Discussion Questions

1. Should the participants have been told how future contact would be made?
2. Should an attempt be made to contact study subjects who did not give a relative or a friend's contact information?

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Part 2

In trying to locate participants, Bob found that some of the subjects' contact information was invalid. He contacted directory assistance in an attempt to get new telephone numbers. For those with unlisted numbers or no information in directory assistance, Bob used the Internet to search. If these two methods did not produce valid information, he contacted the clinic where the study took place. However, some of the study subjects were no longer patients at the clinic. Bob then referred to the question that asked for subjects' contact information. However, not all of these sources had good contact information. During the approval process, the institutional review board (IRB) never discussed the issue or agreed that providing contact information on a relative or friend would imply consent for follow-up contact at any time.

In an effort to locate subjects to complete the data and please the principal investigator, who wants to conduct a follow-up study, Bob decided to use a credit bureau to trace the subjects for a small charge. The subjects' names, addresses and phone numbers with invalid contact information, including those who did not give a relative's or friend's contact information, were sent to a credit bureau. Bob was happy to learn that the credit search produced new information (including a Social Security number) for about a fifth of the missing subjects. But there were still a number of subjects to locate.

Discussion Questions

3. Should the IRB have been asked to approve use of a credit bureau to locate missing subjects?
4. Should Bob have sent subjects' contact information to a credit bureau?
5. Should the study subjects have been told during the initial informed consent phase that a credit bureau would be used to contact them if necessary?
6. Should the participants' Social Security numbers have been obtained and used to locate them?

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Part 3

Bob learned that another credit bureau provides software to use for searches, and he ordered it. In using this software, Bob learned that every time a credit search is run on someone, it has the potential to lower the person's credit rating. He also found out that his company's name was listed on the report, and he purchased an option from the software company that would exclude the company's name from the report.

Discussion Questions

7. Should Bob's company have ordered the software for in-house tracing of study subjects?
8. Should Bob's company have prevented its name from appearing on the credit reports?
9. Did use of a credit bureau and credit search software jeopardize the confidentiality of the subjects' contact information?

Notes

Brian Schrag, ed., *Research Ethics: Cases and Commentaries, Volume 5*, Bloomington, Indiana: Association for Practical and Professional Ethics, 2001.

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Resource Type

Case Study / Scenario

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Graduate Research Ethics: Cases and Commentaries - Volume 5, 2001

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Publisher

Association for Practical and Professional Ethics

Authoring Institution

Association for Practical and Professional Ethics (APPE)