Brian Schrag's Commentary on "PI or Private Investigator"

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Nature of the study

It is not clear from the case description whether this project was initially designed as a longitudinal study with expected follow-up research (or at least data collection) or whether it simply intended to allow for the possibility of follow-up, perhaps to clarify information or to do further research. What does seem clear, given the fact that the initial consent form mentioned the possibility of re-contact, is that the follow-up contact was not simply someone's afterthought several years after the study was completed. It appears that a clear decision to do this particular follow-up seems to have been made years after the end of the study.

It is also not clear if this study was therapeutic or nontherapeutic. If it was a therapeutic study, there might be reasons to follow up with subjects for their benefit. I shall assume for the purposes of the discussion that it was a nontherapeutic study and hence the re-contact of subjects was not for their welfare.

Ethical Issues

The case raises a number of issues. Is the mere contacting of subjects years after a study is completed an ethical issue, does such an action require obtaining informed consent? Is the means of relocating subjects of a study years after the study is complete an ethical issue, and does that activity require informed consent? Should such issues have been addressed in the original study protocol? Having failed to address such issues adequately in the initial protocol, what ought to be done at later stages?

What we do know in this case is that the attempt to re-contact former subjects did have consequences for them. Some of the participants were contacted without their knowledge of the process or consent. Some participants may have been re-contacted against their wishes and without their consent. Some experienced an invasion of their privacy. Information on subjects' credit ratings was apparently obtained by the study manager and perhaps shared with others. A smaller group may have had their credit ratings harmed without their knowledge or consent. Merely participating in the original study made them vulnerable to harms inflicted by the researcher that had nothing to do with the content of the study.

Is the mere contacting of study participants years after the study has been completed an ethical issue? Some subjects may know from the outset that they do not wish to be contacted after the end of a study. Mere participation in a study does not mean one has surrendered any rights to be left alone or to have one's privacy respected in subsequent years. Much can happen to subjects in the interval after a study is completed. Depending on the study, there may be a variety of reasons subjects may wish not to be contacted. For example, they may not want their current intimate contacts to know they had participated in the study. They may simply prefer to not be disturbed, and that itself is a moral reason for them not to be contacted. For these considerations, researchers are morally required to obtain informed consent from such subjects for future contact.

Is the means of locating persons, even those who have given consent to be recontacted, an ethical issue? Clearly it is. Would anyone consent to allow a researcher to use a credit bureau to track one down, particularly if that negatively affects one's credit rating? Surely not. It would not occur to most of us that was a possibility. But the possibility does underline the fact that there are limits to what we would agree to in terms of procedures used to track us down, even if we give consent to be re-contacted.

Without knowledge of the nature of the study, the need for follow up or any therapeutic value to the participants, it is difficult to fully assess the moral seriousness of the actions in this case or to suggest what actions ought to be taken at later stages of the case. However, it is sometimes better to exercise preventive ethics, to take steps to avoid the ethical issues from arising rather that trying to solve the ethical problems after the fact. Adequate informed consent procedures established during the study could have gone a long way toward avoiding the ethical

issues raised in this case.

Informed Consent

Since the possibility of re-contacting subjects was anticipated from the beginning of the study, the investigators should have proposed a much more carefully thought out informed consent procedure to ensure that participants clearly gave their informed consent to be re-contacted.

Although the form mentioned the *possibility* of re-contact, it is not clear how explicit the request for permission to re-contact was, nor whether there was a blurring of the distinction between 1) consent to participate in this study and 2) consent to be contacted in the indefinite future for some unspecified purpose. It may well be that consent to participate in the study ought to be separated from consent to be re-contacted sometime in the indefinite future for some unspecified purpose. Participants may have been willing to participate but not willing to consent to re-contact. Some did not provide contact information, and it is not clear whether that should be interpreted as agreeing to participate in the current study but refusing to be re-contacted.

If re-contact is (less likely) actually the initiation of a new study, then it is not clear that it is appropriate to combine the informed consent to participate in the original study with consent to participate sometime in the future in a study of unspecified nature. The informed consent information presumably supplied details only for this study and, even if adequate to obtain informed consent for this study, could not be adequate for consent to an unspecified later study. Given these uncertainties, it is not at all clear that the informed consent for future contact was actually adequate for any of the subjects. It is even less clear that it was adequate for those who gave no future contact information.

If we assume the protocol should have included obtaining a clear and independent informed consent to re-contact, what would be reasonable for the researchers to say, regarding the method of contact, in order for the consent to be informed?

If one is contemplating the task of contacting subjects three years after completion of the original study, it should be obvious to the researchers from the start that some systematic procedure to locate subjects will need to be followed. (If the size of

the pool is such that data would be useful only if virtually everyone in the study can be contacted, then it may not be wise to plan on re-contact unless an ethical means of successfully contacting all subjects is possible.) Obviously, the method outlined in the protocol was inadequate: Asking participants to list next of kin or other contacts did not produce a complete initial list of contacts.

One possibility would be to institute a tracking system to update contact information on a regular basis - every six months, for example. Each update would include and constitute a renewed permission to maintain contact.

However it is to be done, if the researchers expected to get informed consent for re-contacting subjects, they had an obligation to anticipate the difficulty of locating subjects and design a protocol accordingly. It does not take a rocket scientist to recognize there are acceptable and ethical ways of locating people and unethical and unacceptable ways of locating people. Obviously, technology is changing rapidly, and there may be possibilities of violating privacy in order to find contact information that were not thought of at the original point of consent. Nevertheless, the informed consent should include some assurances that the means used to find participants will stop short of violating their privacy or other interests.

Given all this, the researchers had an obligation to devise an informed consent form that would inform subjects of the purposes of re-contacting them in the future and the procedures that would be used to locate them. If the researchers failed to provide that in the protocol, the IRB had an obligation to raise the issue. Neither of them did so in this case.

Later stages of the case

Having failed to obtain an adequate informed consent for re-contact at the time of the study, what, if anything, should be done three years later when the researcher decides to do a follow-up study?

The researchers might use the contact information provided by subjects in the first place. There is, in the original consent form, at least a fig leaf of informed consent to be recontacted. If that strategy does not yield enough subjects for the study, the researchers should return to the IRB with a proposal for locating subjects for whom contact has been lost. It is the researchers' responsibility to obtain that approval

from the IRB. It is the obligation of the IRB to see that the methods proposed to locate subject do not violate their interests. The researchers are also responsible for overseeing the actions of the study manager. It is clearly not the responsibility of the study manager to devise procedures on his own.

If no ethical means can be developed for locating subjects, then the study using these subjects should be abandoned. It may be that failure to find and contact the subjects means this study cannot go forward, and some useful or important information may be lost. It is not the case that the importance of the work automatically outweighs the means used to find the subjects merely because the technological means of locating the subjects are at hand. Poor initial planning and design by the PI are the reasons for the lost knowledge. That cannot be an excuse for the later unethical treatment of subjects.