RESEARCH ETHICS

Keep people informed or leave them alone? A suggested tool for identifying research participants who rightly want only limited information

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People taking part in research vary in the extent to which they understand information concerning their participation. Since they may choose to limit the time and effort spent on such information, lack of understanding is not necessarily an ethical problem. Researchers who notice a lack of understanding are in the quandary of not knowing whether this is due to flaws in the information process or to participants’ deliberate choices. We argue that the two explanations call for different responses.

A tool for identifying those research participants who want limited information is presented. This consists of a restricted number of questions about trust in and appraisal of research, priority of time and privacy, and perception of a duty to participate. It is argued that an important group of participants who purposely lack understanding of the study can be identified with this tool. Some limitations to this approach are also discussed.
Research participants requiring only limited information

Trust
A reasonable assumption about the people we need to identify, and about people in general, is that, unless they trust the research community and current ethical review procedures, they will not participate in research without finding out as much as they can about the study in question. If they do not trust medical researchers in general, or at any rate the researchers carrying out the specific study, the odds are that they will be unwilling to participate in any research at all. If they are prepared to consider it, this is most likely on condition that they can assure themselves that the risk involved in their participation is acceptable, that the aim of the study is worth while, etc. This they can do in two ways, either by reassuring themselves of the study’s quality by examining available relevant information, or by allowing their representatives on an ethics review committee or some other comparable body to carry out this review for them. If they trust medical research and the ethical review system, then they may find it less important to obtain every piece of information in order to make an informed judgement themselves. They may feel that this is already taken care of, and that this is how it should be.

High priority for time and privacy
People who put their trust in research may nevertheless wish to have detailed information if they are to participate in a research study. Every participant would like to know in some detail what will happen to them—for example, whether they are at risk and what burdens they will face by taking part. However, the information given to research participants is typically much more detailed and comprehensive than that. One may expect most reasonable prospective participants to pay close attention to such information. If they do not, one can anticipate that they will have some reason for not making the effort. One such reason, typical in an age of hectic living and information overload, is that people want to save time. Another closely related reason is that they want to minimise outside interferences, or at least guarantee a fair amount of private time and space. People who trust medical research and give high priority to privacy and time saving may have nothing against participating in a research study on condition that doing so will occupy just a minimum of their time. They are most interested in the effort and personal amount of time required and not very interested in other details concerning participation.

Since research participants may value their own time and privacy highly but nevertheless want a lot of information about the study, we need a formulation in our identifying tool that distinguishes between this category and those who want as little inconvenience as possible. We therefore suggest that the phrase “Limits to my participation are important” is included in the statement concerning time and privacy.

Valuing research
Even if the kind of people we discuss have no reason not to participate under the conditions just mentioned, they have as yet no reason to participate. However, if they appreciate medical research, then they do. A person who values medical research in general is more likely to decide to participate in a study if asked. Such people are also more likely to decide to take part in research even if they happen to value their time dearly, while those with strong time or non-interference preferences who do not value research highly are unlikely to participate.

A duty to participate
Unless people believe that they have some personal responsibility for helping out, they may both trust the research community and value medical research highly, but still be unwilling to make any personal contribution, especially if they have strong time or privacy preferences. On the other hand, if a sense of personal responsibility is present, they may

Components of the tool of identification
For the statements to function as an identifying tool, the answers must correctly detect persons who exhibit poor understanding because they have chosen to limit their involvement in the informed consent process. Can a common set of characteristics be identified? What we need to analyse is such persons’ attitudes towards research participation. In the following we (1) list what we believe to be essential themes that the statements we have in mind must cover, (2) try to formulate the specific statements, and (3) discuss to what extent knowing the answers to these statements could do the job.

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We do not believe that a more differentiated set of responses is needed in order to achieve a useful pattern of answers, there is no reason for both that these people trust the research system and that the researchers are trusted. Unless there are clear indications then a limited interest in the information about the study. Thus, the only answer that can be relevant this trust cannot be expected to be willing to participate in a thorough understanding of a study. An “I fully agree” answer to the statements about valuing research and having a personal duty to contribute nevertheless strengthens the assumption that a person belongs to the category we are trying to identify, because it strengthens the picture of that person as someone who chooses to participate for a reason. Even an “I agree to some extent” to one or both of these statements lends some, albeit weaker, support to the view that the decision to participate is grounded in a genuine choice.

If people neither value medical research nor think they have a duty to contribute, then it is less clear why they would participate. Of course, they may do it because they think it will benefit themselves. After all, a number of studies have shown that there is an “inclusion benefit” for those participating in well controlled clinical experiments compared with patients given the usual treatment. Since the assumption that participation will be of personal benefit may be incorrect in specific cases, some people may indeed require a deeper understanding of the study and of what it means to research participants.

The third and fourth statements, about valuing research and having a personal duty to contribute, concern motivation to participate. In principle, potential research participants may have a number of other reasons for being willing to take part, reasons too numerous to list in a short section on the information sheet. These other reasons do not necessarily rest on mistaken beliefs and may constitute good grounds for participation. This makes the answers to the third and fourth statements less important. Yet, if answered by “I fully agree” or “I agree to some extent”, they indicate (with varying strength depending on the answer) some reasonable grounds for participating.

Thus, the ideal profile for the kind of persons we want to identify, in order to protect them from the unwanted attentions of researchers who are concerned lest they be insufficiently informed, includes a definite affirmative response to all four statements, but the response “I agree to some extent” to one or both of the last two statements still helps to identify the type of person we seek. The identifying responses are given in box 2.

**Box 1** To what extent do you agree with the following statements?

- I trust medical research as it is conducted today.
- Limits to my participation are important because I value my own time and privacy highly.
- I greatly value the medical research performed in this country today.
- I think that, if one can, one should contribute to the progress of medicine by participating in medical studies when asked.

**CATEGORIES FALLING OUTSIDE THE CATEGORY**

Unfortunately, it is easy to produce a number of “profiles” that show a similar interest in receiving no more than minimum information but which do not meet our specifications. For instance, there may be those who do not agree at all that medical research is valuable, but who nevertheless decide to participate in a study. Some may do it out of a sense...
they do not want to face. For example, some people may not agree with the information. They do not want to be informed, and sometimes evade responsibility by not obtaining as much information as they can. In other words, they may fully agree to take part in a study, but who decide to participate out of curiosity, not out of kindness towards those asking them, or for a whole range of other reasons.

Another kind of profile that we fail to identify is that of people who are willing to take considerable risks. Such persons may not trust the research system and may still not be interested in obtaining more than minimal information about the study; to this kind of person, the risks involved are simply no cause for concern.

Even if certain individuals replying negatively to the proposed statements belong to the “should not get renewed information” category, the evidence for their being in this category is insufficient for those managing a study if based solely on our proposed tool. People may have good reasons for their standpoint, and probably should receive only the information necessary for completion of the study, but our tool does not identify them convincingly.

These limitations are regrettable. We are nevertheless willing to accept them since we cannot conceive of a practical way to cover all or most of these possible reasons. We believe that our tool identifies the largest group of people who should not be bothered with renewed information, but it fails to identify other groups.

Another type of objection to our approach is that people sometimes evade responsibility by not obtaining as much information as they can. In other words, they may fully agree with all four statements but there is another explanation for their not regarding the information. They do not want to understand because that would make demands on them that they do not want to face. For example, some people may not want to confront the fact that their disease is genetic by nature and thus may also affect their children, because unconsciously they find this too great a burden to bear.

The remedy is to differentiate between more or less important information. In this article we argue that researchers should not interfere with people’s privacy or ignore their autonomous decisions to settle for a limited understanding, but this principle must be balanced against other important values, such as benevolence and security. There is a professional obligation to act benevolently and refrain from exposing patients to unnecessary risks of harm; researchers must therefore judge in each case according to whether the nature of the information makes special demands on the understanding required of research participants.

CONCLUSIONS

This article was prompted basically by the recognition that the lack of understanding about a study among its research participants is not necessarily a problem. It is a problem if the lack of understanding is due to poor or inadequately communicated information, but not if it stems from the research participants deliberately choosing not to make the effort needed to acquire that understanding. Additional efforts on behalf of the researchers directed towards providing information to research participants who have chosen to limit their involvement and understanding are unethical because they intrude, for no good reason, on these people’s privacy and infringe their autonomy.

We have specified a number of statements that may be used jointly to identify research participants who appreciate modern medical research and want to make their contribution, but who wish their participation to interfere as little as possible with their ordinary lives. They trust the medical research system to consider their interests seriously, and therefore do not feel the need to know about the details of the study. If those in this category can be identified at the outset of the study, when they sign the consent form, the researchers can avoid encroaching on these participants’ privacy later on if there are indications of a lack of understanding of the study among them, or if additional information of a non-essential nature becomes available.

Clearly, there is a need for empirical investigation into these matters—for example, to see whether there really are clear-cut monitors and bluters among research participants. Furthermore, although we have argued that our tool is reasonable, it still requires validation.

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