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.
Information as possible or whether they settle for a minimum. Owing to this consideration, which ultimately rests on respect for individuals’ autonomy and personal integrity (treated as important intrinsic values), there is a need to identify, in a non-intruding way, those participants who want only a minimum of information. Note that the underlying reasons are exactly those that are normally appealed to in arguments claiming that people should be given more information if they lack knowledge about the study in which they are participating. If people should be informed out of respect for autonomy and personal integrity, then not informing them further if these values would otherwise be disrespected must also be important. Although the moral harm of one person receiving an unwanted brochure may be quite limited when taken in isolation, a systematic lack of adjustment to what information research participants want displays a serious lack of respect for them as individuals. This may test the trust that many people feel in medical research today, which, in turn, may make future research more difficult to carry out because people could become less willing to participate.

Why not just ask participants about their attitudes towards receiving more information later on? This may seem the most convenient way to distinguish those who should not be bothered from those who want an extended informational contract. However, there are two good reasons against following this suggestion. First, experience shows that such simple questions give notoriously unreliable results. They are—for example, prone to bias because of participants’ wishes to please the interrogator, and there is also the risk of respondents not considering all aspects that they find important—because they do not happen to think of them—before delivering an answer. Secondly, such questions may cause psychological distress. We can easily imagine people becoming worried about what information they will not receive if they answer “no” when asked, perhaps thinking about what possible reasons an investigator may have to ask such a question in the first place (“What do they want to hide from me?”). We conclude that there is a need for a more reliable and discrete identification tool.

This article suggests such a tool. The basic idea is to pinpoint the participants who already want limited information at the outset by allowing them all to respond to a few specific statements on the occasion when they receive information and sign the consent form. The tool is not foolproof, but by carefully designing criteria for identification we try to show that it is possible to distinguish those who want more information from those who do not.

The legality of this tool may vary from country to country. In this article we leave the legal issue aside and focus on the moral question of whether such a tool, if legally permissible, should be used by researchers.

**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.

**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 assuring 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 overkill, 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
We do not believe that a more differentiated set of responses is needed in order to achieve a useful pattern of answers, especially since we try to identify individuals with a clear set of preferences. It is argued that unless there are clear indications that these people trust the research system and that the researchers are trusted, much of the effort put into recruiting new potential research participants may have been wasted. Furthermore, it is argued that unless 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.

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.

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

Cases 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...
of duty, others may deny having a duty to participate but may participate anyway, for other reasons.

For an illustration, consider the following example: Mr NN is a very busy man who has great confidence in the research community; he does not doubt for one second that he would not be exposed to more than very limited risks were he to participate in a study. However, he is very sceptical about the usefulness (and therefore, in his own eyes, value) of academic medical research, and he does not believe he has any duty whatsoever to participate in such studies. He nevertheless decides to participate in a medical study for kicks. If nothing else, it gives him something to talk about at the formal dinners he sometimes attends. Certainly, there may be people like NN, even though those who do not value medical research in general are likely to be unwilling to participate in such studies. One can also imagine people who share the views of NN about research value and personal responsibility, but who decide to participate out of curiosity, 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 responding 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 risk 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 enroaching 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 blusters among research participants. Furthermore, although we have argued that our tool is reasonable, it still requires validation.

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REFERENCES


Wendler D. Can we ensure that all research subjects give valid consent? Arch Intern Med 2004;164:2201–4.


Doyal L. Journals should not publish research to which patients have not given fully informed consent—with three exceptions. BMJ 1997;314:1107–11.


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