

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 sometimes show a lack of understanding of the information conveyed.^{1–3} Our research team has recently reported that participants in a longitudinal medical study claim to be *satisfied* with the information they have received and find it *sufficient* for an informed decision, yet tests show their knowledge of the study to be poor in some respects.⁴ Is lack of understanding always sufficient reason for renewed information efforts? In this article, we suggest that it is not.

One possible explanation for the lack of understanding among research participants is that there are flaws in the information process. The information may not contain all the relevant components, too much may be given, or it may not be successfully communicated.⁵ Consent forms run the risk of being incomprehensible, for instance by being too compact or by using complicated language.^{6–7} Such flaws may result in serious misunderstandings⁸ and “irrational” decision making behaviour (what psychologists call “biases and heuristics”).⁹ When the information process is deficient, this is cause for ethical concern, and renewed and improved information efforts may be needed.¹⁰ The idea that there is a need for renewed information correlates with a shift from regarding the very giving of information as the most important component of informed consent to a view whereby giving of information and the corresponding apprehension of it are perceived as parts of a process that may be stretched over time.^{11–12} Often the notion of a “testing stage”, a follow-up by which patient or participant understanding is assured, is viewed as an essential part of the process.¹³ (Steve Clark notes that prominent medical ethicists such as Stephen Wear, Faden and Beauchamp are prone to advocate such models of informed consent.¹⁴) Some commentators even subscribe to an ideal of “fully informed consent”.¹⁵

However, there are other plausible explanations as to why research participants lack understanding apart from flaws in the information process. The one we focus on here is that they may have a limited understanding of the study owing to a conscious choice to disregard some, or much, of the information given to them. For instance, they may find only a few aspects of the study relevant to their choice of whether to participate or not, while additional information is beside the point for them, even though it may be considered relevant by

others. This difference between people's informational preferences has been viewed as a difference between “monitors” and “blunters”.¹⁶ Monitors desire voluminous information while blunters distract themselves from such information. If it is the case that some research participants are blunters and lack understanding because they have chosen this way, then this may not present an information problem.

However, some information about a research study may be so important that it is in the long term interest of participants to know about it regardless of their present preferences. For instance, this would be the case if the study involved considerable risk to the participants. People often consent to participation in research while having very vague conceptions of the risks entailed.¹⁷ In such circumstances, their interest in safety and avoidance of risk is more important than respect for a desire to remain ignorant. Out of beneficence they should be informed even if they have expressed a wish not to be informed.¹⁸

Some participants may lack understanding because this is their choice, while others lack understanding because the information was not presented in a way that was comprehensible to them. Since both types of explanation are plausible, when there are such indications, researchers need to find out why their research participants have limited understanding of the study in question. Yet the problem cannot generally be solved by simply asking the participants, because if the lack of understanding is due to a conscious choice to minimise involvement, then additional contacts made by researchers may be regarded as an unwelcome intrusion into participants' private lives.

The ethical consideration that forms the point of departure for this article is that it is unethical to burden research participants unnecessarily with more information than they want. Those who accept and desire only a minimum of information should not be contacted by researchers for other reasons than those necessary for the success of the study or for the protection of the participants. It is not necessary in this sense to give renewed information or to contact these participants in order to check whether they feel they need more information, or even to subject them initially to comprehension measurements. We owe them respect as moral agents regardless of whether they want as much

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 contact. 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

decide to participate although they value their own time and private life dearly. Such a feeling of responsibility may, for example, come from them viewing themselves as citizens with an obligation to society or from the realization that as patients the care they receive will depend on the willingness of others to contribute to the advancement of medical science, and therefore that every patient should in return try to contribute to the future development of the discipline.¹⁹

STATEMENTS TO BE CONSIDERED

If these considerations are the relevant ones, how are we to formulate the corresponding statements that are to be submitted to participants? We suggest the statements listed in box 1.

We also suggest that the respondents are given the following three alternatives to each statement:

- I fully agree;
- I agree to some extent;
- I do not agree.

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.

HOW THE ANSWERS SHOULD BE USED

Assuming that the statements are responded to by all participants, how should they be used? Under what conditions can it be concluded that a participant belongs to the category whose members we want to identify? What can be said about the assumption that all people in this category have some basic rationality and share a fairly “normal” outlook on the world? (We will return to some less common points of view below.)

First, it seems to be a necessary condition that there be no doubt about whether they trust the researchers involved in the study. Such trust may spring from a general trust vis-à-vis the medical research community. People who do not have this trust cannot be expected to be willing to participate in research without having a strong grasp of what is happening. They would most likely want to be thoroughly informed about the study. Thus, the only answer that can be relevant here is: “I fully agree”.

If people agree to participate, for whatever reasons, but want to minimise the time and effort spent on the study, then a limited interest in the information about the study might be expected. As mentioned, this also presupposes that the researchers are trusted. Unless there are clear indications both that these people trust the research system and that they have priorities that limit their interest in achieving a thorough understanding of the study, there is no reason for attributing their limited understanding of the study to

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.

deliberate choice. Therefore, an “I fully agree” answer to the statement about time and privacy is also needed.

If people value medical research highly and believe they have a personal duty to contribute when an opportunity clearly presents itself, this undoubtedly increases the likelihood that they will be willing to participate in a medical study. However, valuing research and feeling that they have this duty says nothing in itself about whether or not they also take a personal interest in research, and therefore want to know a lot about it. Valuing research and thinking one has a duty to participate when the opportunity is given are independent of the attitude towards doing what it takes to obtain 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.^{20–22} 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.

If the reasoning so far is correct, a person belonging to the category whose members we want to identify will fully agree with the statements about trust and time/privacy. This is a necessary condition. If individuals trust the researchers somewhat or agree somewhat with the statement that they prefer to limit the commitment to the study needed on their behalf, then there is insufficient reason for concluding that they belong to the category.

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.

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

Box 2 Category identifying responses

- Trust
 - I fully agree
- Time/privacy
 - I fully agree
- Valuing research
 - I fully agree
 - I agree to some extent
- Responsibility to contribute
 - I fully agree
 - I agree to some extent

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 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 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 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 blunters among research participants. Furthermore, although we have argued that our tool is reasonable, it still requires validation.

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