NRES SHARED SINGLE ISSUE ETHICAL DEBATE - ISSUE PAPER ONE - TIME TO CONSENT

1. Introduction

Issue One was debated by 24 RECs during a single ethical debate. The RECs involved came up with a shared view broadly line with current guidance, they felt consent must be informed, voluntary and time given to consideration to participate needs to be thought through on a case by case basis having considered the influencing factors presented by the research and the participant group. The factors highlighted as influencing decision making are set out in the conclusion to this paper and form a useful template for review.

2. The Issue- How long should potential participants have to consider the invitation to join a research project?

Do we need to delay decisions about participation in research or should the patient have the right to choose to make an immediate decision? What are the deciding factors when making a decision, and are there different rules for different circumstances?

3. Current Guidance

Guidance to applicants in the Integrated Research Application system:

Question A31 Time allowed to decide whether to take part

- Potential participants need time to consider fully the implications of taking part in research. They should be able to ask questions and reflect. Participants should not be rushed into decisions.
- There are no fixed guidelines. Each study should be considered on its own merits, the more burdensome studies will require a longer time for deliberation. Consent for short studies such as questionnaire based studies could be obtained much more quickly. Pragmatic considerations are also needed particularly when subjects have travelled long distances.

NRES guidance on information sheets

10.1 Summary
Information is the most important decision aid. Surveys indicate that those approached to participate want material on which they can make a decision but many wish to share the decision with their health care professional. The need for trust is still evident. This process is much more than provision of an information sheet and a signature on a consent form and a recent review of evidence indicated (not surprisingly) that talking one–to–one was the most effective way to provide information that was understood. This could be scheduled in (possibly with the length of time this might be expected to take) and explained at the beginning of any printed information. Subjects need time to ask questions and reflect. There is no exact defined time for this, Time provided needs to be commensurate with the research, shorter or longer. Researchers need to explain to RECs how they will do this and it will help their application if they describe their skills and training. When recruiting participants to a clinical trial, it can be difficult."

World Medical Association Declaration of Helsinki, Clinical Trials Regulations
No specific time is referred to.

Medical Research Council (UK) Guidance for Good Clinical Practice in Clinical Trials
This states that adequate time should be given to the potential participant to consider the information without specifying a time.

Research Governance Framework for Health and Social Care
This suggests time to consent is agreed between the participant and the researcher rather than being a pre agreed specified time

General Medical Council (UK) Research: the role and responsibilities of doctors
GMC guidance states that doctors should allow potential participants sufficient time to reflect on the implications of participating, provide further any further information they request and not put anyone under any pressure to participate but it does not specify a time period for consent.

Post recruitment confirmation of informed consent by SMS
Technology exists to follow up any subjects who have provided quick consent. These authors describe an idea to check willingness to participate in research by SMS messaging after 24 hours. If practical considerations limit the time to consider this might be useful. 553 were approached, 530 gave initial consent, 8 later regretted giving consent, a small number but captured by this method

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4. Conclusion

RECs taking part broadly agreed there should be flexibility when deciding the appropriate time to consent and that it was important to consider each case individually. RECs did vary in where they sat on this issue; some RECs leaned more towards giving more time to consent as a default and only considering exceptions if there was evidence to justify it while other RECs were happy to largely leave it to the participants to decide consent time. Others felt more immediate consent was the acceptable default unless there was an important reason to offer more time. RECs felt it was important to give sufficient information within the application for the REC to make a decision about consent time.
The views of RECs broadly were in line with current guidance and felt reference to a specific consent time e.g. 24 hours may be unhelpful. Consent must be informed and voluntary and time given to consideration needs to be thought through for each study.

In their discussions RECs established the following factors influence the appropriate time to consent. These issues present a useful template for decision making and include:

a. The type of research involved. As a general rule the more complex or interventional the study the longer time is needed to consent and even a cooling off period could be provided to allow the potential participant to change their mind.

b. The desire to avoid participants feeling coerced into taking part. It should be noted when considering this some RECs felt an influencing factor was who will take consent.

c. Views, convenience and welfare of participants. This should take into consideration the patient’s right to choose when they consent including the right to choose immediate consent, the treatment needs of participants as well as their desire to share information about the research with their family or GP

d. The level of understanding of the participants. This can be influenced both by the complexity of the study (including the complexity of the patient information) and the participants groups taking part. RECs recognised some patient groups are extremely well informed and have the necessary information to make more immediate choices.

e. The setting of the research. This could influence the situation by making a need for immediate consent e.g. in emergency setting such as A&E or may influence the need to gain more time to consent e.g. if the research involved a vulnerable group or when a patient had just been given bad news.

f. Consideration of risk of harm including potential for delay of instigation of treatment against possible benefits

g. Other Factors influencing the decision. These include when screening to the study will take place and the fact that more time may give more gravitas to the research.