What potential research participants want to know about research: a systematic review

Helen Michelle Kirkby,1 Melanie Calvert,1 Heather Draper,2 Thomas Keeley,1 Sue Wilson1

ABSTRACT

Objective: To establish the empirical evidence base for the information that participants want to know about medical research and to assess how this relates to current guidance from the National Research Ethics Service (NRES).

Data sources: Medline, Web of Science, Applied Social Sciences Index and Abstracts, Sociological abstracts, Health Management Information Consortium, Cochrane Library, thesis index’s, grey literature databases, reference and cited article lists, key journals, Google Scholar and correspondence with expert authors.

Study selection: Original research studies published between 1950 and October 2010 that asked potential participants to indicate how much or what types of information they wanted to be told about a research study or asked them to rate the importance of a specific piece of information were included.

Study appraisal and synthesis methods: Studies were appraised based on the generalisability of results to the UK potential participant population. A metadata analysis using basic thematic analysis was used to split results from papers into themes based on the sections of information that NRES recommends should be included in a participant information sheet.

Results: 14 studies were included. Of the 20 pieces of information that NRES recommend should be included in patient information sheets for research pooled proportions could be calculated for seven themes. Results showed that potential participants wanted to be offered information about result dissemination (91% (95% CI 85% to 95%)), investigator conflicts of interest (48% (95% CI 27% to 69%)), the purpose of the study (76% (95% CI 27% to 100%)), voluntariness (39% (95% CI 2% to 100%)), how long the research would last (61% (95% CI 16% to 97%)), potential benefits (57% (95% CI 7% to 98%)) and confidentiality (44% (95% CI 10% to 82%)). The level of detail participants wanted to know was not explored comprehensively in the studies. There was no empirical evidence to support the level of information provision required by participants on the remaining seven items.

Conclusions: There is limited empirical evidence on what potential participants want to know about research. The existing empirical evidence suggests that individuals may have very different needs and a more tailored evidence-based approach may be necessary.

INTRODUCTION

Medical research is central to the advancement of treatments, services and technology.1–3 Potential participants have the right to choose whether they participate in medical research,4,5 and individuals must give their consent prior to participating in research. As part of this ongoing process,
potential participants must be provided with sufficient information to make a voluntary and informed decision.\(^2\)\(^5\)\(^6\)\(^7\)\(^8\)\(^9\)\(^10\)\(^11\) In research settings, study information is usually conveyed to potential participants in the form of a written participant information sheet (PIS), which is later reinforced by a verbal consent interview with a member of the research team.\(^12\)

In the UK, the National Research Ethics Service (NRES) provides extensive guidance on how a PIS should be written and presented. The guidance suggests that a PIS should be split into two parts where part one provides a brief and clear explanation of the essential elements of the specific study and allows participants to make an initial choice of whether the study is of interest. Part two should then contain additional information on matters such as confidentiality, indemnity and publication intentions.

There is some concern that PIS have become increasingly lengthy over recent years.\(^10\)\(^13\)\(^14\) Complex studies, for example, where the potential participant might, for example, on the basis of test results be invited to participate in a further phase of the study, often use detailed and lengthy PISs. This can lead to poor understanding by participants\(^15\)\(^16\)\(^17\) and a corresponding concern that consent criteria are not always met. The NRES guidance is not explicit in the level of detail to be included in a PIS, and there is disagreement among experts about how much information to include.\(^18\) If PISs become so complex that only the most confident and educated participants are able to digest all the information, this may result in selection bias meaning that research is less generalisable.\(^15\) Furthermore, there is a risk that healthcare researchers are becoming increasingly paternalistic in their information provision without recognising individual participant needs. In order to help address the problem of how much information to include in PIS, we conducted a systematic review that aimed to establish the empirical evidence base for the information that potential participants want to know when they are deciding about participation.

**METHODS**
**Selection criteria and literature search**

This systematic review included all studies that asked participants to indicate how much or what type of information they wanted to be told about a research study or asked them to rate the importance of a specific piece of information. We included studies published between 1950 and 27 October 2010 with no limit to language or participant group. We only included studies of participant opinion and excluded studies of healthcare professional or other expert opinion.

We combined Mesh terms Patient, Research Subjects, Consent forms, Informed Consent and Research ethics with terms relating to information provision (online appendix 1). We conducted searches in Medline, Web of Science, Applied Social Sciences Index and Abstracts, Sociological abstracts, Health Management Information Consortium and the Cochrane Library electronic databases. We also searched thesis index’s, grey Literature databases, reference and cited article lists, key journals and Google Scholar and we asked expert authors to identify relevant studies.

We did not conduct a formal quality assessment of included literature because there were both quantitative and qualitative studies, widely varied study methods and different types of results that were often not comparable between papers. Instead, we conducted a critical appraisal of each paper using five quality indicators (response rate, sample size, demographics, participant characteristics and strengths and limitations of study methods). The strengths and limitations of each study are presented in table 1.

**Data extraction and synthesis**

One researcher (HMK) extracted data from papers using a pre-defined data extraction sheet and a second researcher (TK) checked it for accuracy with disagreements resolved by discussion between these two authors (table 1). A metadata analysis using basic thematic analysis was used to analyse the data from the 14 papers. Themes were based on the sections of information that NRES recommends should be included in a PIS (table 2).\(^10\) Each paper was assessed to identify any further themes relating to what information research participants may want to know. A metadata analysis coded individual results based on their relevance to each theme and then themes were collated to report overall results. For themes where more than one quantitative study reported a proportion of participants wanting to know the information, pooled proportions with random effects were calculated using StatsDirect statistical software (StatsDirect Ltd).

**RESULTS**

The search yielded 11943 unique references. We discarded 11291 after reviewing the title, 620 after reviewing the abstract and a further 18 after reviewing the full paper (figure 1). HMK conducted the citation screening and TK independently validated approximately 10% of the references identified from electronic databases (96.0% κ agreement rate). All 14 included studies were identified from searches of Medline and Applied Social Sciences Index and Abstracts. Expert authors identified 37 unique references; 13 were duplicates from the electronic searches and 24 did not meet the inclusion criteria.

Of the 14 studies included in the review, three specifically considered the return of research results to participants and six considered only investigator conflicts of interest. Five studies looked broadly at what information potential research participants wanted to know.

Of the 20 sections of information NRES suggest should be included in a PIS, there were seven categories where no empirical evidence was identified that
<table>
<thead>
<tr>
<th>Lead author/country/year</th>
<th>Inclusion/exclusion criteria</th>
<th>Participant illness</th>
<th>Participant demographics</th>
<th>Total number of participants (response rate)</th>
<th>Study design</th>
<th>Sampling strategy</th>
<th>Analysis</th>
<th>Key themes explored</th>
<th>Study strengths</th>
<th>Study limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walkup, USA, 2009</td>
<td>None provided</td>
<td>None</td>
<td>Gender: not reported</td>
<td>57 (not provided)</td>
<td>Exploration of conversation and questionnaire</td>
<td>Convenience</td>
<td>Descriptive summary statistics</td>
<td>Study purpose, voluntariness, study method, risks, benefits, confidentiality and review board approval</td>
<td>Participants approached in a public setting and invited to complete a questionnaire and researcher recorded study information spontaneously requested Did not specify a disease group</td>
<td>No inclusion/exclusion criteria Participant demographics not reported</td>
</tr>
<tr>
<td>Bento, Brazil, 2008</td>
<td>Female participants aged 18–49 years who had taken part in a clinical trial of women’s health in the previous 12 months and lived in Metropolitan area of Campinas, Sao Paulo, Brazil</td>
<td>Women’s health</td>
<td>Gender: only female Age: 18–49 Education/ deprivation: 4 focus groups 8th grade or less, 4 focus groups above 8th grade education Ethnicity: not reported</td>
<td>51 participants 8 focus groups (not provided)</td>
<td>Focus groups</td>
<td>Convenience</td>
<td>Framework analysis</td>
<td>Study methods, risks and benefits</td>
<td>Participants of different ages and educational level likely to have different needs and opinions regarding topic Focus groups homogeneous for age and educational level; suitable to ensure they were comfortable expressing opinions Recruitment continued until data saturation point</td>
<td>Demographics not representative of the general population as the study only included women and was limited to participants from a trial of a contraceptive intervention</td>
</tr>
<tr>
<td>Lead author/country/year</td>
<td>Inclusion/exclusion criteria</td>
<td>Participant illness</td>
<td>Patient demographics</td>
<td>Total number of participants (response rate)</td>
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<tr>
<td>Hutchinson, Australia, 1996</td>
<td>Participants of clinical trials of COPD, asthma, diabetes, osteoporosis, rheumatoid arthritis and the influenza vaccine. Excluded if clinical trial for acute, life-threatening or debilitating conditions with inadequate therapy</td>
<td>Chronic illness</td>
<td>Gender: 52% male Age: median age 70 (range not reported) Education/deprivation: range of backgrounds Ethnictiy: not reported</td>
<td>259/324 (80%)</td>
<td>Questionnaire</td>
<td>Convenience</td>
<td>Descriptive summary statistics and multivariate logistic regression</td>
<td>Conflicts of interest (CoI) organisation and funding of the research</td>
<td></td>
<td>Demographics not representative of the general population as median age 70</td>
</tr>
<tr>
<td>Gray, USA, 2007</td>
<td>Participants enrolled onto a phase I research trial, spoke English and were medically and mentally capable of participating</td>
<td>Phase I research trial</td>
<td>Gender: 52% male Age: median age 61 (range 26–82) Education/deprivation: range of backgrounds Ethnicity: 81% white</td>
<td>102/119 (86%)</td>
<td>Questionnaire</td>
<td>Consecutive participants enrolling onto parent trial</td>
<td>Descriptive summary statistics, $\chi^2$ tests and multivariate logistic regression</td>
<td>CoI organisation and funding of the research</td>
<td>Same interviewer conducted all interviews</td>
<td>Demographics not representative of the general population as the median age was 61 and was limited to cancer patients participating in an early phase clinical trial</td>
</tr>
</tbody>
</table>

Continued
### Table 1  Continued

<table>
<thead>
<tr>
<th>Lead author/country/year</th>
<th>Inclusion/exclusion criteria</th>
<th>Participant illness</th>
<th>Participant demographics</th>
<th>Total number of participants (response rate)</th>
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</thead>
<tbody>
<tr>
<td>Fernandez, 23 Canada, 2007</td>
<td>English-speaking adolescent with cancer or parents of children with cancer. Excluded acutely unwell or recently relapsed</td>
<td>Cancer</td>
<td>Gender: adolescents not reported Parents mostly women (23/30; 77%)</td>
<td>40/43—10 adolescent, 30 parent participants (93%)</td>
<td>Questionnaire</td>
<td>Random</td>
<td>Descriptive summary statistics and χ² tests</td>
<td>Return of study results</td>
<td>Demographics not representative of general population as participants were well educated, mostly Caucasian and limited to adolescents with cancer/parents of children with cancer</td>
<td></td>
</tr>
</tbody>
</table>

*Age: adolescents median age 16 (range 13–20) Parents median age 40.9 (range 28–53) Education/deprivation: adolescents predominantly in education (no figures reported) Parents 50% with post secondary education* 
*Ethnicity: adolescents 80% Caucasian Parents 100% Caucasian*
### Table 1 (Continued)

<table>
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<tr>
<th>Lead author/country/year</th>
<th>Inclusion/exclusion criteria</th>
<th>Total number of participants (response rate)</th>
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<th>Analysis</th>
<th>Study design</th>
<th>Sampling strategy</th>
</tr>
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<tbody>
<tr>
<td>Bento, USA, 2006</td>
<td>Participants of HIV, hepatitis, arthritis and surgical oncology trials who were &gt; 18 years and English speaking</td>
<td>33 (not provided)</td>
<td>Various Gender: 61% male</td>
<td>Face-to-face semi-structured interviews</td>
<td>Convenience</td>
<td>Transcripts coded and themes and major concepts identified</td>
<td>Open questions used during interviews</td>
</tr>
<tr>
<td>Hampson, USA, 2006</td>
<td>Cancer and enrolled in a clinical trial who were English speaking and &gt; 18 years</td>
<td>252/272 (93%)</td>
<td>Various Gender: 56% male, Age: not reported, Education/deprivation: 50-59; 26%, 60-69; 16%, &gt;70; Ethnicity: 92% white</td>
<td>Structured face-to-face interviews</td>
<td>Not provided</td>
<td>Descriptive statistics and Fishers exact test/Kruskal-Wallis test</td>
<td>Validated interview questions</td>
</tr>
</tbody>
</table>

**Study strengths**
- Used hypothetical scenario
- Demographics not representative of general population as participants were more often men and limited to adults participating in HIV, hepatitis, arthritis or surgical oncology trials

**Study limitations**
- Open questions used during interviews
- Data collection continued to saturation point
- Two authors independently conducted analysis

**Notes**
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<tr>
<td>Weinfurt, USA, 2006</td>
<td>Healthy adults or those with a mild chronic illness. Excluded if they had participated in another focus group within the previous 6 months or were working or had worked for an organisation involved in the conduct of clinical trials.</td>
<td>Gender: 42% male; Age: 12%, 18–29; 51%, 30–49; 37%, &gt;50; Education/ deprivation: well educated and financially secure; Ethnicity: 56% white</td>
<td>16 focus groups (not provided)</td>
<td>Focus groups</td>
<td>Convenience</td>
<td>Initial content codes based on transcripts developed that were summarised and reviewed to identify main themes</td>
<td>COI/ organisation and funding of the research</td>
<td>Participants not limited to disease group</td>
<td>Only one moderator conducted focus groups. Non-verbal communication not recorded. Demographics not representative of general population as the study population were well educated, financially secure and the majority had previously shown interest in research.</td>
<td></td>
</tr>
<tr>
<td>Partridge, USA, 2005</td>
<td>All participants of the parent trial (chemotherapy trial)</td>
<td>Gender: only female; Age: mean age 55 (range not reported); Education/ deprivation: range of backgrounds; Ethnicity: 96% white</td>
<td>94/135 (69.6%)</td>
<td>Questionnaire</td>
<td>Convenience</td>
<td>Simple descriptive statistics</td>
<td>Return of study results</td>
<td>Participant selection biased towards participants that wanted to know study results. Demographics not representative of general population as the study population were mostly Caucasian, only included females and was limited to participants of a breast cancer trial</td>
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<tr>
<td>Kim, USA, 2004</td>
<td>Potential research participants &gt;18 years, diagnosed with heart disease, breast cancer or depression and listed on the Harris Interactive Chronic Illness Database</td>
<td>Various</td>
<td>Gender: 50% male Age: 4% 18–29, 16% 30–44, 61% 45–64, 19% 65+ Education/deprivation: range of backgrounds Ethnicity: 92% white</td>
<td>5478/20205 (27%)</td>
<td>Online questionnaire</td>
<td>Random</td>
<td>Two-way ANOVA modified for ordinal data and multinomial logistic regression</td>
<td>Validated questionnaire Participants chosen at random but from the subset of those registered on the Harris Interactive Chronic Illness Database</td>
<td>Voluntariness, study methods, expenses, risks and the drug/device/procedure being tested</td>
<td>Demographics not representative of general population as it was limited to internet users</td>
</tr>
<tr>
<td>Partridge, USA, 2003</td>
<td>Any participant enrolled into the parent study (chemotherapy trial)</td>
<td>Breast cancer</td>
<td>Gender: not reported Age: median age 54 (range 29–82) Education/deprivation: range of backgrounds Ethnicity: 84% white</td>
<td>51/55 (93%)</td>
<td>Questionnaire</td>
<td>Convenience</td>
<td>Simple descriptive statistics</td>
<td>Return of study results</td>
<td>Multicentre Unvalidated questionnaire Demographics not representative of general population as the study was limited to participants of a breast cancer trial. Gender was not presented but expect most were women given disease area</td>
<td></td>
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<tr>
<td>Casarett, USA, 2001</td>
<td>Participants with a current telephone number, enrolled at a pain clinic, who had chronic non-malignant pain, were taking scheduled opioids and had experienced the pain for at least 6 months</td>
<td>Chronic pain</td>
<td>Gender: 40% male Age: mean age 47 (range 30–86) Education/deprivation: range of backgrounds Ethnicity: 85% white</td>
<td>40/86 (46.5%)</td>
<td>Semi-structured telephone interviews</td>
<td>Convenience</td>
<td>Descriptive summary statistics and bivariate analysis with non-parametric tests Voluntariness, study methods, expenses, risks and the drug/device/procedure being tested Validated interview topic guide Questions spontaneously asked by participants were recorded</td>
<td>What potential participants want to know about research</td>
<td>Multicentre Unvalidated questionnaire Demographics not representative of general population as participants were more often men and limited to chronic pain patients</td>
<td></td>
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<tr>
<td>Lead author/country/year</td>
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<td>Maslin, UK, 1994</td>
<td>213/300 (71%)</td>
<td>Attending a breast unit and were patients with a breast cancer diagnosis or asymptomatic women with a family history of breast cancer</td>
<td>Cancer Gender: only female</td>
<td>Age: median 47 (range 24–81) Education/ deprivation: not reported</td>
<td>Postal questionnaire</td>
<td>Random descriptive statistics</td>
<td>Simple study purpose, voluntariness, confidentiality</td>
<td>Studypurpose, voluntariness, study methods, risks, benefits and confidentiality</td>
<td>Participants chosen at random but from a subset of those attending a breast unit but were limited to those with breast cancer</td>
<td></td>
</tr>
<tr>
<td>Sand, Norway, 2008</td>
<td>213/333 (64%)</td>
<td>Participants eligible for the parent study (all lung cancer patients)</td>
<td>Cancer Gender: 57% male</td>
<td>Age: median 69 (range 44–84) Education/ deprivation: range of backgrounds</td>
<td>Semi-structured interviews</td>
<td>Convenience Identification and categorisation of themes and analysis</td>
<td>Voluntariness, study methods and treatment alternatives</td>
<td>No inclusion/exclusion criteria stated but 11 potential participants were not invited</td>
<td>Demographics not representative of the general population as participants were more often male, had a median age of 69 years and were limited to lung cancer patients</td>
<td></td>
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</tbody>
</table>

# Table 2  Empirical evidence linked to NRES participant information sheet recommended headings

<table>
<thead>
<tr>
<th>NRES Heading</th>
<th>What does NRES say should be included</th>
<th>Number of studies</th>
<th>Empirical evidence for inclusion in PIS from literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the purpose of the study?</td>
<td>Purpose is an important consideration for subjects and should be included</td>
<td>2&lt;sup&gt;23&lt;/sup&gt;</td>
<td>Pooled results showed that 76% (95% CI 27% to 100%) participants wanted to know about study purpose. No empirical evidence.</td>
</tr>
<tr>
<td>Why have I been invited?</td>
<td>Why and how participants have been chosen and how many will be in the study</td>
<td>0</td>
<td>Pooled results from the 3 quantitative studies&lt;sup&gt;20&lt;/sup&gt; 30  29 showed that 93% (95% CI 2% to 100%) participants wanted to know about voluntariness. The one qualitative study reported that it was the most important piece of information to be included in a participant information sheet.&lt;sup&gt;31&lt;/sup&gt;</td>
</tr>
<tr>
<td>Do I have to take part? / What will happen if I don't want to carry on with the study?</td>
<td>The voluntary nature of the research should be included</td>
<td>4&lt;sup&gt;21&lt;/sup&gt;-32</td>
<td>Pooled results from all three studies&lt;sup&gt;20&lt;/sup&gt; 30  29 showed that 61% (95% CI 16% to 97%) participants wanted to know how long the research would last. 68% (27/40; 95% CI 53% to 82%) wanted to know the frequency of additional study visits&lt;sup&gt;29&lt;/sup&gt;</td>
</tr>
<tr>
<td>What will happen to me if I take part? / What will I have to do?</td>
<td>How long the participant will be involved in the research / how long the research will last</td>
<td>3&lt;sup&gt;21&lt;/sup&gt;&lt;sup&gt;32&lt;/sup&gt;</td>
<td>No empirical evidence. Specific information types varied considerably between studies, so no meaningful pooled results could be calculated. The proportion of people wanting to know what would happen to them ranged from 9.5% (2/21; 95% CI 0% to 22.1%)&lt;sup&gt;31&lt;/sup&gt; to 20% (8/40; 95% CI 7.6% to 32.4%)&lt;sup&gt;29&lt;/sup&gt; depending on what the specific information was. For example, 20% (8/40; 95% CI 7.6% to 32.4%) wanted to know about burdens to friends or family caused by study participation.&lt;sup&gt;29&lt;/sup&gt; 12% (5/40; 95% CI 2.3% to 22.8%) wanted to know how much work they would miss because of study participation.&lt;sup&gt;29&lt;/sup&gt; 10% (4/40; 95% CI 0.7% to 19.3%) wanted to know how much time would be spent waiting in clinic during study visits&lt;sup&gt;29&lt;/sup&gt; and 9.5% (2/21; 95% CI –3% to 22.1%) wanted to know practical information about trial procedures&lt;sup&gt;31&lt;/sup&gt;</td>
</tr>
<tr>
<td>Expenses and payments</td>
<td>Expense claims available and if there is any kind of payment for participation</td>
<td>1&lt;sup&gt;21&lt;/sup&gt;</td>
<td>25% (10/40; 95% CI 11.6% to 38.4%) wanted to know if free medication would be available during or after trial.&lt;sup&gt;29&lt;/sup&gt;</td>
</tr>
<tr>
<td>What is the drug, device or procedure that is being tested?</td>
<td>Short description of the drug, device or procedure and given the stage of development state the dosage of the drug and method of administration, and details of any contraindicated drugs included over the counter drugs</td>
<td>2&lt;sup&gt;21&lt;/sup&gt;&lt;sup&gt;31&lt;/sup&gt;</td>
<td>The one quantitative study&lt;sup&gt;29&lt;/sup&gt; showed that specific questions about the medication regime ranged from 25% (10/40; 95% CI 11.5% to 38.4%) that wanted to know what control they had over medication dose during the study to 70% (28/40; 95% CI 55.8% to 84.2%) that wanted to know the frequency with which study medication must be taken.&lt;sup&gt;29&lt;/sup&gt; The study also showed that 62% (25/40; 95% CI 47.5% to 77.5%) wanted results of previous studies of safety and 45% (18/40; 95% CI 29.5% to 60.4%) of efficacy, and 15% (6/40; 95% CI 3.9% to 26.1%) wanted to know if study medication had been approved for clinical use&lt;sup&gt;29&lt;/sup&gt;</td>
</tr>
</tbody>
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<tr>
<th>NRES Heading</th>
<th>What does NRES say should be included?</th>
<th>Number of studies</th>
<th>Empirical evidence for inclusion in PIS from literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are the alternatives for diagnosis or treatment?</td>
<td>What other managements/treatments are available and a list of all important comparative risks and benefit</td>
<td>1&lt;sup&gt;22&lt;/sup&gt;</td>
<td>5% (1/21; 95% CI 0% to 13.9%) wanted as much information about treatment alternatives as they received about the study medication&lt;sup&gt;31&lt;/sup&gt;</td>
</tr>
<tr>
<td>What are the possible disadvantages and risks of taking part?/What are the possible side effects of any treatment received when taking part?</td>
<td>Any risks, discomforts or inconvenience should be outlined</td>
<td>4&lt;sup&gt;16 23 31 32&lt;/sup&gt;</td>
<td>Specific information types varied considerably between studies so no meaningful pooled results could be calculated. Results ranged from no participants that asked about study risks (0/57)&lt;sup&gt;20&lt;/sup&gt; to 97% (207/213; 95% CI 95% to 99.4%) who wanted to be informed about any possible emotional or physical discomforts and side effects&lt;sup&gt;30&lt;/sup&gt;</td>
</tr>
<tr>
<td>Radiation and the Ionising Radiation Regulations</td>
<td>If the use of additional ionising radiation is required as part of the study, then information must be given to the participant on the radiation involved</td>
<td>0</td>
<td>No empirical evidence</td>
</tr>
<tr>
<td>Harm to the unborn child: therapeutic studies</td>
<td>Clear warnings must be given where there could be harm to an unborn child, if there was a risk in breast feeding or if taking the medication is likely to cause fertility problems</td>
<td>0</td>
<td>No empirical evidence</td>
</tr>
<tr>
<td>What are the possible benefits of taking part?</td>
<td>Benefits should be included, but where there is no intended clinical benefit it should be stated clearly</td>
<td>3&lt;sup&gt;23 31 32&lt;/sup&gt;</td>
<td>Pooled results of the two quantitative studies&lt;sup&gt;20 30&lt;/sup&gt; suggest that 57% (95% CI 7% to 98%) wanted to know about study benefits. Two studies provided relevant data relating to specific benefits.&lt;sup&gt;29 31&lt;/sup&gt; Specific requests ranged from 14% (3/21; 95% CI –0.7% to 29.3%) that wanted to know about hopes for better treatment&lt;sup&gt;31&lt;/sup&gt; to 55% (22/40; 95% CI 39.5% to 70.4%) that wanted an opportunity to learn about condition or medication under study.&lt;sup&gt;29&lt;/sup&gt; Specific information types varied considerably between studies so no meaningful pooled results could be calculated. 55% (22/40; 95% CI 39.6% to 70.4%) wanted to know about the availability of medication after the study was over&lt;sup&gt;29&lt;/sup&gt;</td>
</tr>
<tr>
<td>What happens when the research study stops?</td>
<td>Arrangements for after the trial finishes must be given, and it must be clear if participants will have continued access to any benefits or intervention they may have obtained during the research. If treatment will not be available after the study, it should be explained what treatment will be available instead</td>
<td>1&lt;sup&gt;21&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>What if there is a problem?</td>
<td>How complaints will be handled and what redress may be available</td>
<td>0</td>
<td>No empirical evidence</td>
</tr>
<tr>
<td>Will my taking part in the study be kept confidential?</td>
<td>How data will be collected, stored, what it will be used for, who will have access to it, how long it will be retained for and how it will be disposed of</td>
<td>2&lt;sup&gt;23 32&lt;/sup&gt;</td>
<td>Pooled results showed that 44% (95% CI 10% to 82%) participants wanted to be given information about confidentiality and the protection of their privacy</td>
</tr>
</tbody>
</table>

### Table 2  Continued

<table>
<thead>
<tr>
<th>NRES Heading</th>
<th>What does NRES say should be included?</th>
<th>Number of studies</th>
<th>Empirical evidence for inclusion in PIS from literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Involvement of the GP/family doctor</td>
<td>If the participants GP needs to be notified of involvement or asked for consent</td>
<td>0</td>
<td>No empirical evidence</td>
</tr>
<tr>
<td>What will happen to any samples I give?</td>
<td>Clear description of whether new samples will be taken, if excess samples will be taken, and if access to existing stored samples will be required. The same type of information as for data is required to be provided</td>
<td>0</td>
<td>No empirical evidence</td>
</tr>
<tr>
<td>Will any genetic tests be done?</td>
<td>A separate consent form for genetic studies should be used</td>
<td>0</td>
<td>No empirical evidence</td>
</tr>
<tr>
<td>What will happen to the results of the research study?</td>
<td>What will happen to the results of the research, if it is intended to be published and how results will be made available to participants and that they will not be identified in any publication</td>
<td>328 30 33</td>
<td>Pooled results showed that 91% (95% CI 85% to 95%) wanted to know about study results. Specific information types varied considerably between studies, so no meaningful pooled results could be calculated. Two studies provided relevant data relating to specific aspects of what they wanted to know about results.23 28 78% (31/40; 95% CI 64.6% to 90.4%) of participants wanted a description of what researchers had learnt that was important,23 35% (14/40; 95% CI 20.2% to 49.8%) wanted it to include follow-up contacts for the researcher23 and 98% (29/40; 95% CI 58.7% to 86.3%) wanted a list of medical publications written as a results of the research.23 90% (46/51; 95% CI 82% to 98.4%) wanted their family or loved ones to be informed of the results if they were unable to learn them.28</td>
</tr>
</tbody>
</table>

Continued
suggested what information research participants wanted to know (table 2). No further themes, beyond the NRES categories, were identified. We were able to calculate pooled proportions for seven themes. Participants wanted to be told about dissemination of study results (91% (95% CI 85% to 95%)), investigator conflicts of interest (48% (95% CI 27% to 69%)), the purpose of the study (76% (95% CI 67.8% to 83.5%)) wanted to be told about commercial funding,\textsuperscript{27} 69% (3779/5478; 95% CI 67.8% to 70.2%) about personal income,\textsuperscript{27} between 41% (105/259; 95% CI 34.6% to 46.5%) and 82% (4492/5478; 95% CI 81% to 83%) about patents and stocks and shares\textsuperscript{27} 34 and 40% (101/253; 95% CI 34% to 46%) thought researchers should have told participants only about the oversight system\textsuperscript{24}

One study reported that participants wanted to know specifically how money was spent, with proportions ranging from 25% (65/259; 95% CI 19.8% to 30.4%) that wanted to know how much of the funding was spent on administration\textsuperscript{34} to 38% (98/259; 95% CI 31.9% to 43.8%) that wanted to know how spare accrued funds were used at study completion\textsuperscript{34}

One qualitative study reported that participants wanted to know the name of the sponsor\textsuperscript{27} and one quantitative study reported that 57% (148/259; 95% CI 51.1% to 63.2%)\textsuperscript{34} wanted to know the name of the funder.

Some participants wanted help understanding the potential consequences of CoI, some did not\textsuperscript{25} Specific information types varied considerably between studies so no meaningful pooled results could not be calculated

In the absence of empirical evidence to suggest what information potential research participants want, the NRES have based their guidance on expert opinion. It does, however, mean that current information provision for research may not adequately address the informational needs of the general population or ‘hard to reach’ groups such as socially deprived or African–American and minority ethnic groups. While the NRES recognise that one size does not fit all and that low-risk studies with

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<tbody>
<tr>
<td>Who is organising and funding the research?</td>
<td>The organisation or company sponsoring the research and funding the research if these are different and if the researcher conducting the research is being paid</td>
<td>6\textsuperscript{20} 24–27 34</td>
<td>Pooled results from the four quantitative studies showed that 48% (95% CI 27% to 69%) wanted to know about any type of CoI, but there was general disagreement over whether patients wanted to be told about financial CoI. Three studies provided relevant data relating to what participants wanted to know about specific aspects of CoI.\textsuperscript{24} \textsuperscript{27} 34 When financial CoI were broken down into subcategories, 82.5% (4519/5478; 95% CI 81.48% to 83.5%) wanted to be told about commercial funding,\textsuperscript{27} 69% (3779/5478; 95% CI 67.8% to 70.2%) about personal income,\textsuperscript{27} between 41% (105/259; 95% CI 34.6% to 46.5%) and 82% (4492/5478; 95% CI 81% to 83%) about patents and stocks and shares\textsuperscript{27} 34 and 40% (101/253; 95% CI 34% to 46%) thought researchers should have told participants only about the oversight system\textsuperscript{24} One study reported that participants wanted to know specifically how money was spent, with proportions ranging from 25% (65/259; 95% CI 19.8% to 30.4%) that wanted to know how much of the funding was spent on administration\textsuperscript{34} to 38% (98/259; 95% CI 31.9% to 43.8%) that wanted to know how spare accrued funds were used at study completion\textsuperscript{34} One qualitative study reported that participants wanted to know the name of the sponsor\textsuperscript{27} and one quantitative study reported that 57% (148/259; 95% CI 51.1% to 63.2%)\textsuperscript{34} wanted to know the name of the funder. Some participants wanted help understanding the potential consequences of CoI, some did not\textsuperscript{25} Specific information types varied considerably between studies so no meaningful pooled results could not be calculated</td>
</tr>
<tr>
<td>Who has reviewed the study?</td>
<td>Explain the role of the research ethics committees and which committee reviewed the current study</td>
<td>1\textsuperscript{23}</td>
<td>No participants asked about institutional review board approval (0/57)\textsuperscript{20}</td>
</tr>
</tbody>
</table>

GP, general practitioner; NRES, National Research Ethics Service; PIS, participant information sheet.

**DISCUSSION**

Of the 14 papers that met inclusion criteria, five looked broadly at what information research participants wanted to know. These studies focused on the category of information required rather than how much detail participants wanted. All 14 studies had substantial limitations to generalisability when applied to the wider research population because, for example, they focused on specific subsections of the population, for example, six studies included only cancer patients\textsuperscript{23} \textsuperscript{24} \textsuperscript{26} \textsuperscript{28} \textsuperscript{30} \textsuperscript{31} and only one study conducted in the UK.\textsuperscript{30} A number of studies included only women\textsuperscript{21} \textsuperscript{26} \textsuperscript{28} \textsuperscript{30} and participants that were mostly Caucasian\textsuperscript{23} \textsuperscript{26} \textsuperscript{30} and well educated.\textsuperscript{23}–\textsuperscript{25}
little or no intervention may need shorter information sheets, there is little empirical evidence to identify what level of information provision should be made.32 A potential difficulty in conducting research to determine what should be included in a PIS is that an individual’s information preferences may change as they move from being a potential to actual participant.35 36

Responding to individuals’ information needs may prove challenging, but the provision of high-quality appropriate information in a timely manner is crucial to the consent process. Electronic information provision may be one way to address different information needs. Recent research by Antoniou et al37 that allowed participants to access three increasingly detailed levels of information electronically found that the basic level of information was accessed by 70%—82% of participants, but only 9%—18% accessed the level of information currently recommended in NRES guidance and only 3%—12% accessed all three levels of information. Interestingly, 20% (93/552) participants that said they wanted more information even though fewer than this (3%—12%) read all the information available to them.

The study by Antoniou et al37 is an important first step in determining what information potential research participants really want to know when they agree to take part in a study. Further research is required to assess the feasibility and acceptability of unfolding electronic information sheets.

**Limitations**

Ideally, differences in informational requirements for subgroups of the population would have been explored but the small numbers of studies identified and limited data extracted from papers meant this was not feasible.
Conclusions
There is limited empirical evidence as to what information potential participants want to know at the time they are deciding whether or not to participate in research. Real-time studies need to be conducted to explore what information potential participants access when given a choice. This will enable us to determine exactly what information research participants want to know and could, in addition to other sources such as expert opinion, help tailor PIS towards specific population subgroups and enable appropriate high-quality information to be provided to meet individual needs.

Contributors
HMK, MC, SW and HD conceived and designed the research. HMK and TK collected, validated and extracted the data. All authors made substantial contribution to the analysis and interpretation of the data. HMK drafted the manuscript and SW, HD, MC and TK revised it.

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Competing interests
All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) HMK, MC, HD, TK and SW have support from the University of Birmingham for the submitted work; (2) HMK, MC, HD, TK and SW have no relationships that may be relevant to the submitted work; (3) their spouses, partners or children have no financial relationships that may be relevant to the submitted work and (4) HMK, MC, HD, TK and SW have no non-financial interests that may be relevant to the submitted work. HD is an author of one of the papers included discussion.37 SW was also acknowledged.

Data sharing statement
The authors declare that there are no data to share.

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What potential research participants want to know about research: a systematic review

Helen Michelle Kirkby, Melanie Calvert, Heather Draper, Thomas Keeley and Sue Wilson

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