Improving the informed consent process—a booklet on participants’ rights in medical research

Jocelyne R Benatar, Philip McKibbin, Ralph A H Stewart

Abstract

Aim This paper describes the process undertaken to develop and validate a booklet that informs participants of their rights in clinical studies. A booklet coupled with a shorter study-specific informed consent form may improve informed consent.

Methods A booklet was developed in simple clear language, based on information contained in currently used audited informed consent forms and good clinical practice guidelines. 159 people from a broad range of backgrounds with expertise or interest in the consent process were asked to review the booklet and complete a survey. The booklet was modified based on feedback received from 59 respondents.

Results Feedback was used to improve the booklet and ensure it complied with guidelines, was legally accurate and sensitive to tanga te whenua (Māori/indigenous people). The booklet was easier to read and comprehend compared to equivalent information contained in currently used informed consent forms.

Conclusions A broad consultation and revisions improved the booklet and suggested it would be well received if introduced in New Zealand together with shorter study-specific informed consent forms.

Before participating in a clinical study or other medical research, participants must give consent which is competent, informed, comprehending and voluntary.1 The consent process includes a verbal component, which consists of a discussion between the potential participant and the investigator, and a written component—which consists of any documents that are presented to the participant.2 It constitutes all the information that potential participants are asked to consider. However, many individuals either do not read the information and many of those who do read it, do not fully understand it.3–7

Even though good clinical practice guidelines (GCP)8 emphasise the importance of a participant-focussed consent process, the written information presented to potential participants has been increasing both in length and complexity over time.9,10 Some information needed for consent is relevant to all clinical studies.8,11 We proposed that this information, some of which is specific to New Zealand, could be presented in a short booklet which could be given to potential participants together with a shorter, study-specific informed consent form.

The hope is that this would make the written component of the informed consent process more participant oriented by presenting the information common to all clinical studies in an especially readable and comprehensible way.
This study describes the process used to create and validate a booklet on participants’ rights that has a New Zealand focus and which could eventually be implemented across a broad range of clinical studies.

**Methods**

An overview of the steps used to develop and validate the booklet on participant’s rights is presented in Figure 1.

**Figure 1. Overview of the process used to develop and validate a booklet on participant’s rights**

![Diagram showing the process of developing and validating a booklet on participants' rights.](Figure1.png)

+New Zealand guidelines include New Zealand Code of Health and Disability Services Consumers’ Rights and the Medical Councils position statement on informed consent.

*International Guidelines for GCP, 8 the EU directive, 9 FDA regulations 12.

**Booklet development**—The booklet was developed after reviewing contemporary informed consent forms (ICFs); it was revised with reference to GCP, the European Union (EU) directive, Food and Drug Administration (FDA) regulations and New Zealand Code of Health and Disability Services Consumers’ Rights. Our aim was to ensure that the booklet provides information relevant to most or all clinical studies in a simple and readable way and to ensure the information complied with regulatory guidelines.

Table 1 lists information that needs to be included in the booklet and study-specific informed consent form to ensure compliance with GCP.
Table 1. Which information is included in the booklet and which is in the study-specific ICF according to Good Clinical Practice Guidelines

<table>
<thead>
<tr>
<th>Stipulation</th>
<th>Covered by booklet</th>
</tr>
</thead>
<tbody>
<tr>
<td>That the study involves research.</td>
<td>✓</td>
</tr>
<tr>
<td>The purpose of the study.</td>
<td></td>
</tr>
<tr>
<td>The study treatment(s) and the probability for random assignment to each treatment.</td>
<td></td>
</tr>
<tr>
<td>The study procedures to be followed, including all invasive procedures.</td>
<td></td>
</tr>
<tr>
<td>The participant's responsibilities.</td>
<td>Partially</td>
</tr>
<tr>
<td>Those aspects of the study that are experimental.</td>
<td></td>
</tr>
<tr>
<td>The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant.</td>
<td>Partially</td>
</tr>
<tr>
<td>The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this.</td>
<td>Partially</td>
</tr>
<tr>
<td>The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks.</td>
<td>Partially</td>
</tr>
<tr>
<td>The compensation and/or treatment available to the participant in the event of study-related injury.</td>
<td>Partially</td>
</tr>
<tr>
<td>The anticipated prorated payment, if any, to the participant for participating in the study.</td>
<td>Partially</td>
</tr>
<tr>
<td>The anticipated expenses, if any, to the participant for participating in the study.</td>
<td></td>
</tr>
<tr>
<td>That the participant's participation in the study is voluntary and that the participant may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which the participant is otherwise entitled.</td>
<td>✓</td>
</tr>
<tr>
<td>That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of clinical study procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally acceptable representative is authorizing such access.</td>
<td>✓</td>
</tr>
<tr>
<td>That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the study are published, the participant’s identity will remain confidential.</td>
<td>✓</td>
</tr>
<tr>
<td>That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the study.</td>
<td>✓</td>
</tr>
<tr>
<td>The person(s) to contact for further information regarding the study and the rights of study participants, and whom to contact in the event of study-related injury.</td>
<td>✓ (must be completed)</td>
</tr>
<tr>
<td>The foreseeable circumstances and/or reasons under which the participant's participation in the study may be terminated.</td>
<td>✓</td>
</tr>
<tr>
<td>The expected duration of the participant's participation in the study.</td>
<td>✓</td>
</tr>
<tr>
<td>The approximate number of participants involved in the study.</td>
<td>✓</td>
</tr>
</tbody>
</table>
Table 2. Reading scores of approved informed consent forms and the booklet on participant’s rights

<table>
<thead>
<tr>
<th>Variables</th>
<th>21 ethically approved ICFs</th>
<th>Information on participant’s rights</th>
<th>Booklet Information on participant’s rights</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Study-specific information</td>
<td>Mean (SD)</td>
<td>Booklet</td>
</tr>
<tr>
<td>Flesch-Kincaid Grade level*</td>
<td>13 (1.5)</td>
<td>16 (1.7)</td>
<td>11 (NCEA level 2)</td>
</tr>
<tr>
<td>(NZ equivalent)</td>
<td>(First-year university)</td>
<td>(Fourth-year university)</td>
<td></td>
</tr>
<tr>
<td>Flesch-Kincaid Reading Ease score#</td>
<td>40 (7.5)</td>
<td>25 (6.7)</td>
<td>42</td>
</tr>
<tr>
<td>Length (pages)</td>
<td>10 (1.5)</td>
<td>8 (1.3)</td>
<td>8*</td>
</tr>
<tr>
<td>Word count</td>
<td>4392 (1364)</td>
<td>3449 (1117)</td>
<td>1423</td>
</tr>
</tbody>
</table>

* Flesch-Kincaid Grade level. The score relates to the grade level required to read the document e.g. a grade of 12 indicates that the participant needs to be in the highest secondary school year to read the document.

# The Flesch-Kincaid Reading Ease score: the higher the number, the easier a document is to read (comics have a score of 90 and legal documents typically have a score of 10)

+ The booklet has a low word count per page with bullet points. The booklet also contains other information considered helpful to participants, for example, definitions of study terminology and websites for patient advocacy groups

Validation process—The booklets were sent with a sample study-specific informed consent form to 159 people with an interest in the consent process. Among those whose feedback we sought were investigators (n=44) study coordinators (n=38), clinical research organisation members (n=12), pharmaceutical company employees (n=12), research managers (n=6), representatives from the Health and Disability Commission (n=3), ethicists (n=6), ethics committee members (n=10), and lawyers (n=6).

We also sought feedback from Māori (n=14), Pacific Island consultants (n=6), Accident Compensation Corporation (ACC) (n=1) and the refugee council (n=1).

Respondents were asked to complete a questionnaire on the readability and comprehensiveness of specific sections of the booklet, and to indicate whether they thought the booklet, together with the sample study-specific informed consent form, would meet GCP guidelines. The survey also asked ‘Is there any information in the booklet that is missing or unclear?’ Responders were also able to make general comments about the initiative.

Comments were analysed blind to the author and when appropriate revisions were made to the booklet. Additional feedback on a revised version of the booklet was sought from 23 selected respondents.

In addition 30 inpatients and 15 outpatients were asked for feedback on the booklet and study specific informed consent form. Verbal feedback and written comments were obtained, but patients did not complete the study questionnaire.

Comparison of booklet to contemporary informed consent forms—21 ethically approved contemporary informed consent forms were audited for length and readability, and compared to the booklet. All documents were converted to word documents and word count and page length determined using Microsoft Word 2010. 16

Readability was assessed using the Flesch-Kincaid Reading Ease score and grade level score. 17 The Flesch-Kincaid Grade level relates to the grade level required to read the document e.g. a level of 13 indicates that the participant needs to be in year 13 (NCEA level 3) to read the document. The Flesch-Kincaid Reading Ease score relates to how readable a document is; the higher the number, the easier a document is to read (comics typically score 90 and legal documents 10).

Information in the informed consent forms was then divided into study specific information, and general information about participant’s rights. These sections were assessed separately for length and readability.
Results

Feedback—59 of the 159 people who we sent the booklets and a study-specific informed consent form template responded to the questionnaire. Responders included investigators (n=14), study coordinators (n=17), medical doctors (n=11), ethics committee members (n=5), Health and Disability Commission representatives (n=2), lawyers (n=6), Māori consultants(n=5), Pacific Island consultant (n=1), members of Clinical Research organization (CRO) (n=6), ethicists (n=5) and representatives from pharmaceutical companies (n=7).

Overall, the booklet was rated highly for both readability (Figure 2) and comprehensiveness (Figure 3)—with all sections rated as both ‘very readable’ and ‘very comprehensive’ by the majority of respondents. The least readable section was on ‘health care during the study’. Some respondents indicated that they thought the Māori section difficult to read and the information on compensation not involving ACC difficult to understand.

Figure 2. Initial responses to the question: “How readable are these sections in the booklet?”

The majority of people who completed the survey (84%) thought the booklet would satisfy GCP guidelines. Reasons given for not satisfying GCP guidelines included that the information had been oversimplified and the booklets contained inaccuracies. Some responders indicated that adherence to GCP would in part depend on what information was in the study-specific informed consent form.
Changes made to the booklets—Most changes made to the booklet were small, but together they resulted in substantial improvements. The changes that we made are best illustrated with examples. A section headed, ‘Why Do People Participate in Clinical Studies?’ was added which includes the statement, ‘Medical research benefits other people. Sometimes it benefits study participants.’ The sections ‘Your health care’ and ‘Will my own doctor/family doctor be told I am in the study?’, which were rated as more difficult to read, were combined under the heading ‘How will participating in the study affect my healthcare?’.

The information on compensation, which was initially divided between two booklets, was also substantially revised. The statement ‘Injury caused by an investigator may be covered by the investigator’s liability insurance if it is not compensated for by ACC or the sponsor’ was added. Less categorical language was used, and where relevant, statements included instructing potential participants to refer to the study-specific informed consent form for further information.

The section ‘Important information you should know if you identify as Māori’ was also revised, and we agreed with one person’s recommendation that this section should be included in Māori in the English version of the booklet.

Evaluation of currently used informed consent forms—Contemporary New Zealand newspaper articles typically have readability scores of 40 and reading grade scores of 13. Readability scores of the audited informed consent forms are presented in table 2. The average informed consent form is 18 pages long, is difficult to
understand (requiring first year university level), and difficult to read (reading ease score = 30).

The section on participants’ rights specifically has a very low readability score (25) suggesting the equivalent 3 years of tertiary education (grade level 16) are needed to understand it. The section on participant’s rights in ICFs has increased from 4 pages in 2006–2008, to 7.5 pages in 2009–2011.

The revised booklet (accessible at [http://www.nzma.org.nz/journal/125-1362/5344/Booklet.pdf](http://www.nzma.org.nz/journal/125-1362/5344/Booklet.pdf)) has a low word count, a higher readability score (42) and is easier to understand (grade level 11).

**Discussion**

GCP\(^8,10\) states that ‘the language used in the oral and written information about the study… should be as non-technical as practical and should be understandable to the participant or the participant’s legally acceptable representative …’ However, in an audit of 21 contemporary informed consent forms, most were longer than 15 pages, and were relatively difficult to read and understand. A recent audit in America has confirmed that informed consent forms have become increasingly long and incomprehensible.\(^18\)

Extensive use of legalistic language may be because many informed consent forms are crafted overseas to accommodate legal considerations that do not apply in New Zealand.\(^13\) For example, informed consent in the U.S. is heavily informed by the USA.’s ‘Code of Federal Regulations,’\(^12\) a document that contains information that may not apply in New Zealand.

The use of legal language seems to conflict with GCP, which states that “none of the oral and written information concerning the study should contain any language that causes the participant to waive or appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.” The assessment process undertaken by Institutional Review Boards (IRBs) may worsen rather than improve these problems. In an evaluation of informed consent forms for clinical trials assessed by IRBs, most requested changes increased their length, and made them harder to read.\(^19\)

The current New Zealand Health and Disability Ethics Committee guidelines\(^11\) may also contribute by recommending inclusion of lengthy pro forma paragraphs. On the other hand, the proposed recommendation that information on length and readability of documents is included in submissions is an incentive to simplify ICFs.

To those who find informed consent documents difficult to read, the use of legalistic language is likely to be especially confusing. Participants frequently misconstrue the purpose of informed consent documents, perceiving them to be for the protection of investigators, rather than for their own benefit.

**Importance of review and feedback**—It was important that the booklet be developed with the general consensus of stakeholders involved in informed consent in New Zealand. The iterative process used provided the opportunity to craft a booklet that accommodates New Zealand culture\(^20\) and law and is therefore more relevant to
New Zealand participants. Embedding the principles of the Treaty of Waitangi was crucial.

We received many helpful suggestions from Māori groups on how to improve the booklet. Revisions were resent to Māori stakeholders to ensure concordance between groups. The final revised booklet was well received by Māori stakeholders with one responder commenting that the section on Māori was ‘beautifully written’.

The booklet needs to comply with New Zealand and international regulatory requirements, and contain other information relevant to participants. We therefore sought feedback from people with an interest in informed consent, including investigators, study coordinators, or medical doctors. Many comments reflected researchers’ dissatisfaction with the informed consent process as it is currently administered. Overall, respondents were positive about the potential for this booklet to address some of the problems with the informed consent process.

We have developed a template for the study-specific informed consent form to be used with the booklet. Ideally this should be short (no longer than 4–5 pages), use short sentences and contain diagrams of study design.14,17,18,21–28

None of the sections from the booklet should be repeated in the — specific informed consent form. Table 1 provides a list of what needs to be included both in the booklet and the study- specific informed consent form according to GCP guidelines.

Other advantages of the booklet—We see other advantages for the research community in using a booklet which can provide a consistent, nationally accepted approach to presenting general information that all studies could use. It will allow the short study-specific informed consent form to focus on providing participants with relevant, study-specific information in a structured, concise way rather than have this information embedded in a lengthy document. It also will enable ethics committees to focus on study specific informed consent forms, reducing the workload related to reviewing long informed consent forms, consistent with the current aims of the review process of ethics committees.

The presence of booklet, if it was endorsed by the New Zealand Health and Disability Ethics Committee, rather than sponsors should reassure participants that their rights are protected by New Zealand law. The language used is not legalistic and is therefore likely to preclude the misconception that the informed consent form mitigates risk, so it is clear to both investigators and participants that rights are not being abrogated by the giving of consent. Accessible explanations of scientific terms, such as ‘randomisation’, have been included.17

The booklet can be translated into multiple languages while maintaining consistency in the information included, thereby better protecting participants who use English as a second language. Changes to laws regarding rights can be incorporated into the booklet without the need to gain ethics approval for every informed consent form. General availability of the booklet may facilitate discussion on participation in research studies by other health care providers involved in the patient’s care.

Study limitations—Feedback on the booklet was largely qualitative and less than half of those invited responded to the questionnaire. Despite this, we achieved significant feedback from a broad range of professionals with an interest in consent.
This allowed us to establish the acceptability of this approach in NZ, and make important revisions to the booklet. In this report patient responses to the booklet were not evaluated. However, we recently completed a randomised study which compared comprehension using the booklet with that using a typical informed consent form in a large sample of hospital inpatients with favourable results. Results of that study will be reported separately.

This report does not directly address how the booklet would be implemented. Investigators may choose to provide the booklet with a shorter study specific informed consent form for ethics committee review. However, it may be necessary for ethics committees to request the booklet and study-specific informed consent form are used, to prevent sponsors insisting templates crafted in other countries are used.

**Conclusion**

A booklet on participants’ rights was easier to read and comprehend compared to equivalent information contained in currently used informed consent forms. A broad consultation process improved the booklet and suggested it would be well-received if introduced in New Zealand together with shorter study-specific informed consent forms.

**Competing interests:** None of the authors have any conflict of interests to declare in connection with this work.

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**References:**


