

## Improving the Consent Process

### Talking Points

The consent process is considered the cornerstone of human subjects protection. Both the Belmont Report and the federal regulations address informed consent. Neither document gives a clear prescription for the consent process, but they do provide guidance.

- The Belmont Report identifies three elements necessary for informed consent: information, comprehension and voluntariness.
- The regulations address primarily the informational component—providing a list of required elements.

Some critics maintain that IRBs spend too much time on the consent forms rather than other components of the consent process. Although this is a valid concern, the consent form is the element over which IRBs can have most control. However, there are additional ways that IRBs can influence and improve the consent process.

### Improving Informed Consent

In their article entitled *Improving Informed Consent*, Jeff Cooper and Pamela Turner present a model for evaluating and improving the quality of the consent process.

Cooper and Turner identify three elements of informed consent quality to consider.

1. **Structure:** This is the “what” of consent, and includes *tangible elements* such as recruitment materials, consent documents, and other audio or visual information. This is the component that IRBs typically focus on.

IRBs/reviewers can influence and improve this structural component by:

- Ensuring that the information provided in recruitment/consent documents is: 1) accurate, 2) clear, and 3) sufficient. The regulatory list of required elements should be considered as baseline, only. Frequently, it is necessary to require additional information (beyond regulations) to achieve quality informed consent.
- Utilizing consent form checklists during review.
- Providing templates and standardized language for consent documents.
- Measuring reading levels of documents using available tools—such as Flesh-Kincaid.

- Auditing and inspecting consent documents of subjects who have agreed to participate—check to see if approved forms are used and whether they have appropriate signatures.
2. **Process:** refers to *actions* necessary to obtain quality informed consent.
- “Who” provides information and obtains consent? (coercion/undue influence, qualification and training of individuals getting consent)
- “Where” does recruitment and consent occur? (privacy and confidentiality, coercion/undue influence?)
- “When” does recruitment and consent occur? (time sequence, appropriate timing, adequate time to consider?)
- “How” does recruitment and consent occur? (letters, emails, phone calls, group settings?) (are advocates or family members present?) (consent tools such as computers, videos?) (appropriate payments, compensation?)

IRBs/reviewers can influence the process component by:

- Asking for detailed information regarding the consent process in the application.
  - Discussing the consent process directly with research staff.
  - Developing specific institutional policies for subject populations.
  - Observing the consent process. (Federal regulations give IRBs authority to observe, or have a third party observe, the consent process—however, in reality, few IRBs have the time or resources to do this.)
3. **Outcome:** this is the most difficult component to define and measure.

The Belmont Report is clear about the desired outcome of informed consent:

“that subjects, to the extent that they are capable, be given the opportunity to decide what shall or shall not happen to them. Subjects should be provided information, understand the information, and based on their comprehension of the information, make a voluntary decision to participate in research.”

Jeff Cooper points out that comprehension is not just knowledge of information provided, it also requires the subject’s ability to interpret this knowledge and give meaning and significance to it in relation to deciding whether or not to participate.

In a study conducted in 2003 with 441 subjects it was found that, on average, subjects answered less than 2/3 of knowledge questions correctly on a 12-15 item post-consent quiz. It is unrealistic to expect full comprehension of detailed information and we need to be circumspect about how much information we can expect subjects to retain. However, Cooper maintains that there is some information that subjects should fully understand throughout a research study, including:

- that the activity involves research (this is required by regs to be in consent).  
Belmont goes further--states that "the extent and nature of information should be such that persons, knowing that the procedure **is neither necessary for their care nor perhaps fully understood**, can decide whether they wish to participate in the **furthering of knowledge**." It should be clear to subjects that the primary goal of research is to generate data and advance knowledge—not to provide direct benefit to the subject (although it may). This is an important point that is often overlooked in consent forms. Potential subjects are informed that the activity involves research, but often it is not clearly explained that research is not designed for individual benefit.
- that participation is voluntary, and participants may withdraw at any time without penalty (also required by regs).

Other important information that subjects should fully understand:

- the differences between research procedures and standard services or routine care--what will happen to them that would be different if they choose to participate in the research.
- the risks, discomforts and inconveniences involved with participation.

To ensure that this information is clearly presented, it can be useful to have standardized template language for clarity and consistency.

**Examples of Consent Form Template Language:** (Reading level 5.5)

"You are being asked to consider being in a research study. The purpose of this consent form is to help you decide if you want to be in the study. Please read this form carefully and ask study staff to explain any words or information that you do not understand."

"Taking part in this research is your choice. If you decide not to take part, your decision will not affect your regular services or care. You can leave the research at any time."

"The main goal of research is to learn things to help people in the future. We do not know if you will benefit from being in this research study."

According to the findings of the "Subject Interview Study," (cited in Barbara Benson's discussion paper) subjects react differently to the use of words, such as "research," "trial," "study," and "experiment." The word "experiment" was viewed most negatively, while "study" was viewed most positively. Careful consideration should be given to the terms used in describing research to minimize misconceptions about individual benefit.

Another strategy being used by some IRBs to improve outcome is including feedback questions at the end of the consent form to assess comprehension. Typically, these are

used with consent forms for complicated or high risk biomedical research, but they could be helpful in consent forms for any research—and perhaps included in a consent form template.

**Examples of feedback questions:** (Can be modified for specific studies.)

Is the purpose of the research clear?

Do you understand that you may not benefit from being in this research?

Do you understand that participation in this research is voluntary?

Do you understand that you can withdraw from the research at any time without giving a reason and without it affecting your regular care?

Have all your questions about the research been answered?

*If you answered “no” to any of the above questions, or you are unable to answer any of the above questions, you should not sign this consent form.*

## **Summary**

In summary, IRBs cannot influence or control all aspects of the consent process, or the information and words used in verbal consent discussions. It also is unrealistic to expect that subjects will comprehend and retain all, or even most, of the information presented in the consent process. However, IRBs can use a variety of strategies to influence and improve the consent process, including developing appropriate institutional policies, asking specific questions in research applications, and auditing and observing the consent process. IRBs do have control over the information and language used in recruitment and consent documents. Standardized language or text for some sections of the consent form can significantly improve clarity and consistency—such as, a standardized introductory paragraph that clearly presents essential information, including: 1) that the activity involves research, 2) that the goals of research are different from individualized care/services, and 3) that participating in research is voluntary. Feedback questions at the end of consent forms can be a useful strategy to reinforce comprehension of important information and to assess the outcome of the consent process.

## Sources

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