Quality of Informed Consent: a New Measure of Understanding Among Research Subjects

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Background: **The informed consent of participants is ethically and legally required for most research involving human subjects. However, standardized methods for assessing the adequacy of informed consent to research are lacking.** ***Methods and Results:*** **We designed a brief questionnaire, the Quality of Informed Consent (QuIC), to measure subjects' actual (objective) and perceived (subjective) understanding of cancer clinical trials. The QuIC incorporates the basic elements of informed consent specified in federal regulations, assesses the therapeutic misconception (the belief that all aspects of a clinical trial are designed to directly benefit the subject), and employs the language and structure of the new National Cancer Institute template for informed consent documents. We modified the QuIC after receiving feedback from pilot tests with cancer research subjects, as well as validation from two independent expert panels. We then sent the QuIC to 287 adult cancer patients enrolled on phase I, II, or III clinical trials. Two hundred seven subjects (72%) completed the QuIC. To assess test–retest reliability, a random sample of 32 respondents was selected, of whom 17 (53%) completed the questionnaire a second time. The test–retest reliability was good with intraclass correlation coefficients of .66 for tests of objective understanding and .77 for tests of subjective understanding. The current version of the QuIC, which consists of 20 questions for objective understanding and 14 questions for subjective understanding, was tested for time and ease of administration in a sample of nine adult cancer patients. The QuIC required an average of 7.2 minutes to complete.** ***Conclusions:*** **The QuIC is a brief, reliable, and valid questionnaire that holds promise as a standardized way to assess the outcome of the informed consent process in cancer clinical trials. [J Natl Cancer Inst 2001;93: 139–47]**

Clinical trials are critical to advances in the understanding and treatment of cancer. Progress in cancer treatment occurs primarily as a result of clinical research, whether through the modification of existing therapies or through the application of new technologies derived from laboratory investigations. Thus, the challenges of human subjects' protection are integral to oncology *(1–16).*

The informed consent of the subject is ethically required before enrollment in a clinical trial *(17).* Elements of valid informed consent include capacity, disclosure, understanding, voluntariness, and permission *(18,19).* As defined in U.S. regulations governing research with human subjects, informed consent to research includes eight "basic elements" (Table 1) *(20).* In addition, U.S. regulations hold Institutional Review Boards (IRBs) responsible for reviewing most protocols involving human subjects and for ensuring the adequacy of informed consent. However, a recent report by the Office of the Inspector General of the Department of Health and Human Services (Washington, DC) found that IRB review and informed consent requirements might not guarantee adequate protection for human subjects *(21).*

The concept and specifications of informed consent to research derive from ethical and legal theory *(22–25).* In practice, however, assessments of informed consent give cause for concern *(26).* Many studies *(5,27–31)* reveal poor understanding by subjects of both experimental and therapeutic aspects of clinical trials. Indeed, some subjects may not even be aware that they are participating in research *(32,33).* Other subjects may believe the research is conducted primarily for their own benefit rather than for generalizable knowledge or the benefit of future patients *(33).* This belief has been termed the "therapeutic misconception" *(34).*

The cancer research community has contributed to this empiric literature and has taken concerns about informed consent to research seriously *(16).* For example, the National Cancer Institute (NCI) recently convened a working group to recommend improvements in the informed consent process and to enhance the quality of consent forms. The NCI working group published a template designed to simplify and standardize consent forms for subjects' participation in clinical trials *(35).*

Unfortunately, heterogeneous methods of analysis and conceptual difficulties with the definition of informed consent hinder the interpretation and synthesis of the empiric literature on informed consent *(26).* Indeed, despite efforts to develop a standardized assessment tool *(36),* there is no widely accepted method for defining or measuring the outcome of the informed consent process. Because research questions, procedures, risks, and other details vary from one clinical trial to the next, most studies of informed consent have used measurement strategies tailored to the individual trials being evaluated. Such trial-specific methods limit the ability to generalize or to compare the informed consent process across trials. Furthermore, methods to evaluate the informed consent process are costly and require substantial personnel time to administer and/or score questionnaires.

The development of a simple, inexpensive, generic measure of informed consent would have several important benefits. First, it would permit comparison of informed consent across different clinical trials, phases of research, diseases, and research populations. Second, it could be used to evaluate interventions designed to enhance the informed consent process. Finally, it could be used by IRBs as a practical tool to oversee the process and outcome of informed consent *(37,38).*

Because of the importance of informed consent in clinical cancer research, we designed a questionnaire, the Quality of Informed Consent (QuIC), to assess the informed consent process in cancer clinical trials. Our goal was to develop an instru-

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See "Notes" following "References."

ment that would be valid, reliable, inexpensive to use, easy to administer and to score, and appropriate for evaluating different phases of trials. To design the questionnaire, we drew on federal regulations governing research with human subjects *(20),* on theoretical work on the therapeutic misconception by Appelbaum et al. *(34),* and on the recommendations of the NCI's working group *(35).* Our criteria for validity of the instrument were 1) close adherence to existing conceptual work, including widely used definitions of the relevant domains, and 2) consensus among independent experts that it was accurate and comprehensive. In this report, we discuss the development of the QuIC and present data about the operating characteristics and reliability of the instrument.

Methods and Results

Human Subjects Protections

The Dana-Farber Cancer Institute (Boston, MA) IRB approved all stages of questionnaire development involving patient contact.

Conceptual Background

To develop the QuIC, we considered two distinct goals of the informed consent process. The first goal is for subjects to understand their clinical trial well (i.e., *objective understanding*). For example, a subject who enrolls on a randomized trial but is unaware that his/her treatment was selected by chance from two possibilities has a limitation in objective understanding. The second goal is for subjects to believe themselves to be well informed (i.e., *subjective understanding*). For example, subjects should believe that they adequately understand the risks of trial enrollment. Both objective understanding and subjective understanding are important goals of the consent process: Individuals contemplating participation in a trial should both *be* well informed and *feel* well informed about the study under consideration. We, therefore, designed the QuIC in two parts, one to measure objective understanding (part A) and the other to measure subjective understanding (part B).

Item Generation

We used the basic elements of informed consent as outlined in federal regulations as the starting point for the questionnaire *(20).* However, several of these elements (such as "benefits to the subject or to others") are actually composites of two or more conceptually distinct domains. We, therefore, derived 13 independent domains of informed consent, each of which is assessed on both parts A and B of the QuIC, from the eight basic elements specified in federal regulations (Table 1).

For each of the 13 domains, we wrote one or more questions (total, 35 questions) to measure subjects' objective understanding of their clinical trials (part A). Each question consisted of a brief statement about the subject's clinical trial. Responses were initially elicited on a 5-point scale, ranging from *strongly disagree* to *strongly agree.* To avoid agreement bias, we varied the direction of the statements such that for some items *disagree* was the correct response, while for others *agree* was the correct response. Most questions were generic, with one correct answer regardless of the type of clinical trial in which the subject was enrolled. For example, well-informed subjects should always agree with the statement, "If I had not wanted to participate in this clinical trial, I could have declined to sign the consent form." Other questions were phase specific. For example, the statement "In my clinical trial, one of the researchers' major purposes is to find the highest dose of a new drug or treatment that can be given without causing severe side effects" applies only to subjects in phase I trials.

We then generated 15 questions to measure the respondents' subjective understanding of their clinical trials. These questions asked subjects to rate how well they understood each of the domains of informed consent. For example, we asked, "When you signed the consent form to

Table 1. Basic elements of informed consent*

Department of Health and Human Services: basic elements *(20)*	Domain of informed consent (QuIC)	Relevant questions of the QuIC Part A†
1.	A statement that the study involves research	A1
	An explanation of the purposes of the research	A2, A5, A6, A7, and A8‡
	The expected duration of the subject's participation	A3
	A description of the procedures to be followed	A10 and 11§
	Identification of any procedures that are experimental	A4
2.	A description of any reasonably foreseeable risks or discomforts to the subject	A12
3.	A description of any benefits to the subject that may reasonably be expected from the research	A9 and 13
	A description of any benefits to others that may reasonably be expected from the research	A14
4.	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	A16
5.	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained	A15
6.	For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained	A17
7.	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and of whom to contact in the event of a research-related injury to the subject	A18
8.	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue particpation at any time without penalty or loss of benefits to which the subject is otherwise entitled	A19 and A20

*QuIC = quality of informed consent.

†*See* Appendix for text of questions.

‡Questions A6 and A7 apply to phase I studies only, question A8 applies to phase II studies only, and question A5 applies to phase III studies only.

§Questions A10 and A11 are scored differently, depending on whether the subject is in a phase I, II, or III trial.

participate in your clinical trial . . . how well did you understand the treatments and procedures you will undergo"? One additional question asked subjects to assess their overall understanding of the trial in which they were participating. Responses were on a 5-point Likert scale *(39),* anchored by "I didn't understand this at all" and "I understood this very well."

Because the QuIC was intended to be useful across diverse clinical trials, we wrote questions to assess the subject's grasp of important general concepts about clinical research studies. These concepts followed largely from the Department of Health and Human Services basic elements and from the generic purposes and procedures of phase I (toxicity and dose finding), II (preliminary efficacy), and III (randomized controlled) clinical trials *(40).* We did not ask about facts that were specific to individual trials. For example, we did not ask subjects to list the risks to participants, because risks vary widely among trials and such open-ended response formats would require complex, time-consuming, and subjective scoring algorithms. Instead, we simply asked subjects whether they recognized that the trial might involve incremental risks when compared with standard therapy *(34).* To increase content validity, whenever possible, statements were drawn directly from the NCI informed consent template itself *(35).* Finally, we developed several questions that asked about the key contentions of the therapeutic misconception. For example, many subjects may not recognize that the major goal of clinical research is knowledge for the benefit of future patients and that research participation may have potential disadvantages, such as possible increased risk without added benefit, for the individual subject *(34).*

We developed two versions of the questionnaire. The first was designed for adult patients; the second used modified wording (i.e., "your child" rather than "you") and was designed for parents of children enrolled in clinical trials. We ensured that both the adult and pediatric versions of the QuIC were at the eighth-grade reading level, as assessed by the Grammar function of Word 97 for Windows (Microsoft Corp., Redmond, WA).

Content Validity

After developing the questions, we asked three bioethicists with experience in clinical trials methodology and informed consent to review the QuIC for content validity. The consultants independently agreed that the questions addressed the important elements of the informed consent process, that they adequately represented the domains as defined in federal regulations, and that our assignments of correct answers to the questions were appropriate. The consultants' suggestions with regard to the clarity, emphasis and framing of questions, and specification of the response options were incorporated into a revised questionnaire.

After completion of pilot testing (*see below*), we asked three additional experts with experience in statistics, oncology, clinical trial design, and bioethics to evaluate the QuIC. These experts had no previous knowledge of the questionnaire or its development. Each expert was given a copy of the QuIC and asked to indicate the correct answers. Where relevant, the experts were asked to consider only patients in phase I, II, or III trials. We considered the experts' responses as criterion standards by which actual subjects' responses could be judged. Where one expert initially disagreed with the other two about a question, the panel was asked to review that question again to see if agreement could be reached. We obtained consensus for all but one question, which was deleted from the final version of the QuIC.

Pilot Testing of the QuIC

We pilot tested the first version of the QuIC (part A = 35 questions; part B = 15 questions) with a convenience sample of nine subjects (five adult patients and four parents of pediatric patients) enrolled in phase I, II, or III clinical trials at the Dana-Farber Cancer Institute. To assess clarity of questions, we asked the subjects to interpret the meaning of each question and to explain why they chose particular answers. In this first pilot test, summary scores of objective understanding (part A) ranged from 36 to 81 (mean, 59), and scores of subjective understanding (part B) ranged from 60 to 94 (mean, 84). Subjects said that the questions were generally clear, and they interpreted the questions as we intended.

On the basis of subjects' feedback, we made several modifications to the QuIC. First, because the intensity of agreement did not seem meaningful for statements of fact, the response format for questions of objective understanding (part A) was changed from a 5-point scale to a 3-point scale (*disagree, unsure,* and *agree*). Second, we eliminated nine items from part A that the subjects believed were redundant or uninformative, added one item to part A, and eliminated one item from part B. Third, several questions were amended to improve clarity.

After making these changes, we conducted a second pilot test with 10 trial participants (seven adults and three parents of pediatric patients) using the modified QuIC (part A = 27 questions; part B = 14 questions). Subjects' educations ranged from some high school to graduate school. Again, subjects found the questions to be clear and had no difficulty with the modified response feedback. Summary scores of objective understanding ranged from 55 to 96 (mean, 76), and scores of subjective understanding ranged from 32 to 100 (mean, 83). In response to feedback from this group of respondents, three questions on part A were eliminated and several wording changes were made.

Scoring and Weighting of the QuIC

In part A of the final version of the QuIC (see "Appendix" section), each of the 13 domains is addressed by one to three questions. For each question, correct answers are assigned a score of 100 points, incorrect answers are assigned a score of 0 points, and "unsure" is assigned a score of 50 points (because we preferred that subjects recognize areas of uncertainty rather than be certain of false beliefs). Scores for each domain are obtained by averaging the scores for all completed questions in that domain. (The assignment of questions to domains is detailed in Table 1.) Unanswered questions are not scored; if more than half of the questions within a domain are unanswered, the domain score is considered to be missing. The summary score for part A is then calculated by adding the scores for each domain and dividing by the number of nonmissing domain scores (i.e., by 13, if no domain scores are missing). The resulting summary score potentially ranges from 0 to 100; subjects who answered randomly would have an average score of 50. No summary score is calculated if more than half of the domains have missing scores.

To calculate a summary score for part B (subjective understanding), we averaged responses to each of the 14 questions. The raw average (range, 1–5) is then scaled from 0–100 as follows: sum-

mary score = (raw average − 1) × 25. Unanswered questions on part B are considered to be missing.

In designing the scoring algorithms, we considered the possibility that certain domains should carry greater weight than others in determining the summary score. For example, a subject's understanding of the risks of research participation might be more important to an overall assessment of informed consent than his or her knowledge of procedures in the event of a research-related injury. To address the possibility of unequal weighting, we conducted four surveys with convenience samples of 1) 10 cancer patients, 2) 14 research personnel, 3) 14 pediatric oncologists, nurses, and psychosocial clinicians, and 4) six ethics fellows. Subjects were asked to rate the importance of each of the 13 domains on Likert scales *(39).* Most subjects stated that they would consider information about all of the domains to be important to their decisions about enrolling in a clinical trial. Despite altering the presentation and response formats, we were unable to establish meaningful variation in weighting across domains. For example, among patients on clinical trials, we found that mean weights for the 13 domains ranged from 3.9 to 4.9 on a 5-point scale. Differences of this magnitude are unlikely to affect estimates based on the QuIC. The QuIC, therefore, employs equal weighting across domains.

Survey Methods

We then evaluated the revised QuIC (part A = 24 questions; part B = 14 questions) in a larger sample of trial participants. Potential subjects were identified by the Quality Control Center at Dana-Farber/Partners CancerCare, which is responsible for registering all of the patients who enroll in clinical trials at its member institutions. Subjects were eligible if they were greater than or equal to 18 years old and had signed an informed consent form to a qualified cancer clinical trial at Dana-Farber Cancer Institute, Brigham and Women's Hospital, or the Massachusetts General Hospital within the previous 14 days. All open clinical trials were reviewed in advance, and those that evaluated a cancer-directed therapy (i.e., not supportive care) and met strict definitions of phase were considered to be qualified. Specifically, phase I trials needed to be dose-escalation safety studies, phase II trials needed to be single-arm efficacy studies, and phase III trials needed to involve randomization. Subjects were excluded if their consent had been obtained by one of the investigators of the present study or in a language other than English, if their mailing address was outside the United States, or if they died or went off protocol within 14 days of signing the informed consent form for their clinical trial. Enrollment for this study extended from June 1999 to January 2000.

The QuIC either was mailed to the subject's home 3–14 days after the consent form was signed for the clinical trial or, if the subject was hospitalized, was delivered to the hospital room 5–14 days after the consent form was signed. If the completed survey was not returned within 2 weeks, a second questionnaire was sent, along with a postcard on which subjects could indicate their desire not to participate in the study. After an additional 2 weeks, we telephoned nonrespondents to ensure receipt of the questionnaire and to answer any questions about the present study. If the subject requested one, we mailed a third questionnaire. Before each mailing or attempt to contact the subject, we confirmed his/her continued participation in the clinical trial using administrative data. Follow-up questionnaires were not sent to patients who had discontinued participation in their clinical trial (e.g., for reasons of toxicity or disease progression).

Survey Findings

In the next section, we report methodologic issues considered in analyzing the results of this larger survey. Of 287 subjects to whom we sent the revised version of the QuIC, 207 (72%) completed the questionnaire. The mean age of respondents was 55 years. Fifty-five percent of the respondents were female, 91% were white, and 53% had a college education. Twenty-four percent of the respondents were participating in phase I trials, 50% in phase II trials, and 26% in phase III trials.

Differences Between Positive and Negative Questions

We excluded four questions on part A from further analysis because of inappropriateness for the study population or controversy about the correct answer (*see below*). We then evaluated the impact of negative phrasing (i.e., questions for which "disagree" was the correct answer) on subjects' responses to the remaining questions. The raw average across all 20 questions on part A (i.e., without considering domain scores) was 79.7. Subjects scored lower for negative questions than for positive questions (mean, 68.3 versus 85.0, respectively). This difference was of special concern because three of five questions designed to address the therapeutic misconception (A4, A9, and A12) were phrased in the negative, and two (A2 and A13) were phrased in the positive (*see* "Appendix" section). When considered as a group, the mean score for the five questions was 59.4. Although this seemed to indicate the existence of therapeutic misconception among the respondents, we were concerned that the apparently lower scores were simply a function of the subjects' difficulty with negative phrasing. To evaluate this possibility, we adjusted the scores for each question to account for the differences noted between the positive and negative questions. After adjustment, the five therapeutic misconception questions had a mean of 64.1—still markedly lower than the average for all questions—suggesting that the lower scores on these questions were not merely an artifact induced by the format of the QuIC itself. The mean summary score for part B was 87.8.

Test–Retest Reliability

To determine the test–retest reliability of the QuIC, a second copy of the questionnaire was sent to a 20% random sample of respondents. Seventeen (53%) of 32 subjects responded. The subjects completed the second questionnaire a mean of 15.4 days after the first. Respondents to the repeat questionnaire averaged 50 years (range, 35–73 years), 10 (59%) were female, 13 (76%) had a college education, and 15 (88%) were white. Three subjects were enrolled in phase I trials, 11 in phase II trials, and three in phase III trials. Summary scores for part A averaged 77.7 on the initial administration and 79.8 on the repeat administration. The intraclass correlation coefficient (ICC) was .66. There was more test–retest variability among subjects with lower scores than among those with higher scores (Fig. 1). For part B (subjective understanding), summary scores averaged 87.2 on the initial administration and 86.9 on the repeat (Fig. 2). The ICC was .77. Data were analyzed by use of Stata 5.0 for Windows (Stata Corp., College Station, TX).

Final Modifications

Traditionally, phase I clinical trial participants have advanced cancer and no re-

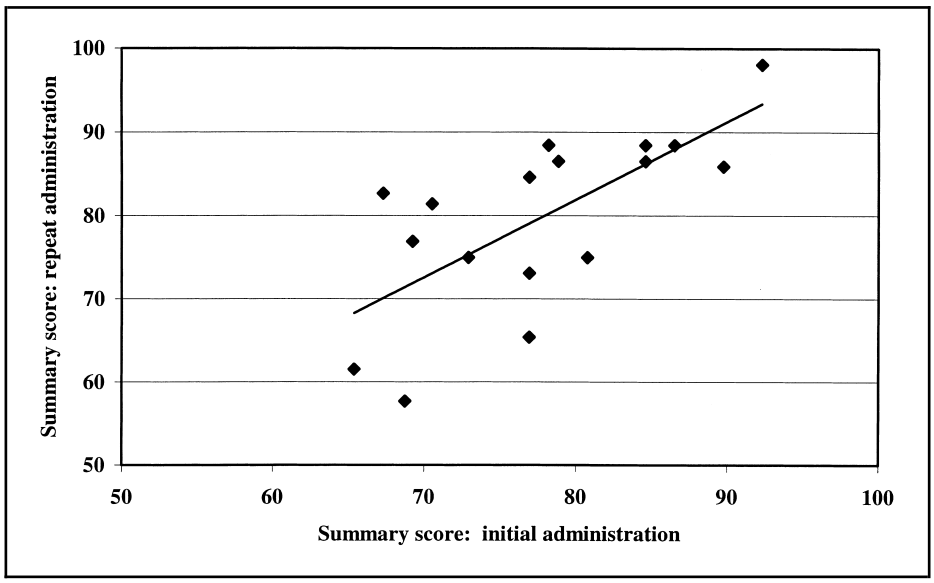

Fig. 1. Test–retest reliability of the Quality of Informed Consent, Part A (tests of objective understanding). The subjects' (n = 17) summary scores on the initial administration are shown on the *x*-axis, and their summary scores for the repeat administration are shown on the *y*-axis. The intraclass correlation coefficient between first and second administrations was .66.

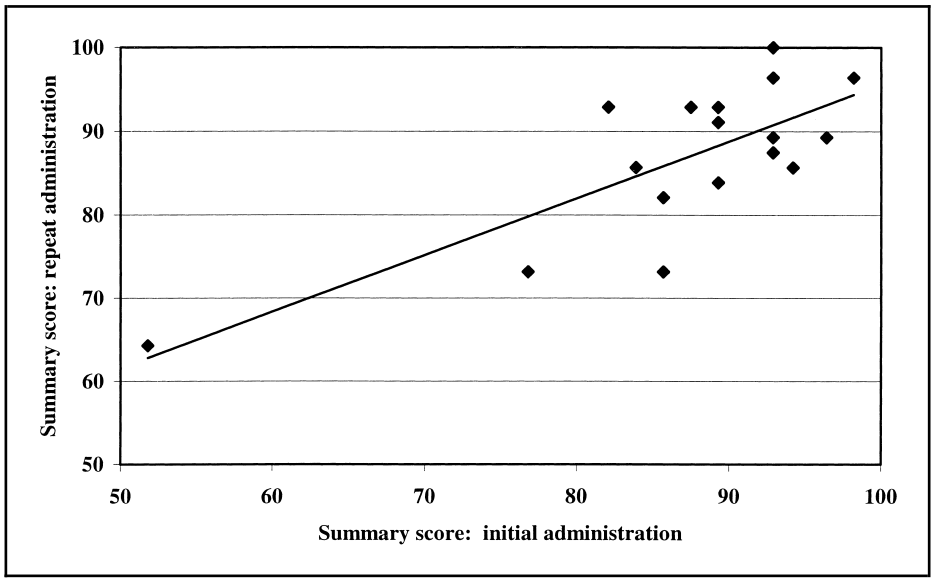

Fig. 2. Test–retest reliability of the Quality of Informed Consent, Part B (tests of subjective understanding). The subjects' (n = 17) summary scores on the initial administration are shown on the *x*-axis, and their summary scores for the repeat administration are shown on the *y*-axis. The intraclass correlation coefficient between first and second administrations was .77.

maining standard treatment options. However, many of the phase I subjects in our sample did not fit this description. We found that dose-escalation/dose-finding designs (together with standard therapy) were also being used to study innovative approaches among potentially curable patients. For example, one study employed escalating doses of chemotherapy together with standard radiotherapy for patients with early-stage breast cancer. We, therefore, determined that three questions originally intended for participants in phase I studies (e.g., Was the option of palliative care presented? Was the goal of the study to cure your cancer?) were inappropriate for many subjects. These questions, in addition to the question identified as problematic by the expert panel of bioethicists (*see above*), were not included in the analyses described here and have been removed from the version of the QuIC recommended for future use.

The final version of the QuIC, which is presented in the "Appendix" section, includes 20 questions in part A and 14 questions in part B. We tested this version for time and ease of administration in a sample of nine adult trial participants, only three of whom had a college education. The mean completion time was 7.2 minutes (range, 2.5–12.8 minutes). Eight of nine subjects rated the questionnaire as "very easy" to complete.

DISCUSSION

Our results suggest that the QuIC is a valid and reliable questionnaire that can be used to assess the quality of understanding achieved by the research informed consent process. The QuIC is easy to administer and employs objective scoring algorithms that are immune to investigator bias. It holds promise in the research setting as an instrument than can be used to compare informed consent across different cancer clinical trials and study populations. It may prove to be particularly useful to investigators wishing to study interventions intended to improve the quality of the informed consent process in cancer clinical trials. Finally, it might also offer a means by which IRBs can monitor the informed consent process within their own jurisdictions.

We ensured face validity and content validity of the QuIC by a rigorous process of instrument development involving definition of domains, item generation, expert review, pilot testing with a varied population of clinical trial subjects, item reduction and modification, and blinded expert confirmation. The development of the QuIC also benefited from the extensive groundwork laid by the NCI's working group. However, the QuIC has several limitations. First, it was developed and pretested in a population of cancer clinical trial participants and, therefore, its wording is cancer specific. Differences between cancer and noncancer clinical trials (i.e., the formal steps and unique populations involved in phase I, II, and III research) suggest that the QuIC should not be used in noncancer settings without further study. Second, because several questions are phase specific, the QuIC would not be appropriate for subjects whose clinical trials employ hybrid designs (i.e., phase I/II or randomized phase II studies). Third, the QuIC is not intended to address all of the important aspects of the informed consent process. Many elements of informed consent, such

as the details of risks and procedures, are trial specific, and no generic instrument could do justice to their complexity. The QuIC may, therefore, be most useful as a core set of questions for informed consent research that requires supplemental trial-specific questions. Fourth, because of the challenging nature of the questions, the QuIC may be more sensitive to the therapeutic misconception than to other areas of subject misunderstanding. Finally, the QuIC needs additional validation in a defined population of cancer clinical trial participants. It will be important to assess whether it is able to distinguish clinically meaningful groups of subjects (e.g., subjects of different educational levels or who have had time to consider their decision compared with those who consented immediately) *(41)*.

The QuIC measures subjects' understanding of their clinical trials rather than disclosure of information or the capacity of the subject to comprehend that information *(19,42)*. However, because understanding is the final common pathway of the informing process, the QuIC can act as a screen for both disclosure and capacity. Where subjects perform well, disclosure and capacity are likely to have been adequate. By contrast, problems with understanding identified by the QuIC might stem from inadequate disclosure, from subjects' pre-existing misconceptions about the nature of clinical research, or from temporary or durable impairments in subjects' capacities.

Despite the limitations noted above, the current version of the QuIC is a short, reliable, and valid measure of the outcome of the informed consent process to cancer clinical trials. It has the potential to permit standardization and comparison of informed consent research across varying clinical settings and may provide a useful tool for IRBs wishing to monitor the consent process in their institutions.

APPENDIX: QUALITY OF INFORMED CONSENT (QuIC), PART A

INSTRUCTIONS: Below you will find several statements about cancer clinical trials (otherwise known as cancer research studies). Thinking about your clinical trial, please read each statement carefully. Then tell us whether you agree with the statement, you disagree with the statement, or you are unsure about the statement by circling the appropriate response. Please respond to each statement as best you can. We are interested in your opinions.

A1.	When I signed the consent form for my current cancer therapy, I knew that I was agreeing to participate in a clinical trial.	Disagree$_1$	Unsure$_2$	Agree$_3$*
A2.	The main reason cancer clinical trials are done is to improve the treatment of future cancer patients.	Disagree$_1$	Unsure$_2$	Agree$_3$*
A3.	I have been informed how long my participation in this clinical trial is likely to last.	Disagree$_1$	Unsure$_2$	Agree$_3$*
A4.	All the treatments and procedures in my clinical trial are standard for my type of cancer.	Disagree$_1$*	Unsure$_2$	Agree$_3$
A5.	In my clinical trial, one of the researchers' major purposes is to compare the effects (good and bad) of two or more different ways of treating patients with my type of cancer, in order to see which is better.†	Disagree$_1$	Unsure$_2$	Agree$_3$*
A6.	In my clinical trial, one of the researchers' major purposes is to test the safety of a new drug or treatment.‡	Disagree$_1$	Unsure$_2$	Agree$_3$*
A7.	In my clinical trial, one of the researchers' major purposes is to find the highest dose of a new drug or treatment that can be given without causing severe side effects.‡	Disagree$_1$	Unsure$_2$	Agree$_3$*

(Appendix Part A continues)

A8.	In my clinical trial, one of the researchers' major purposes is to find out what effects (good and bad) a new treatment has on me and my cancer.[§]	Disagree$_1$	Unsure$_2$	Agree$_{3*}$
A9.	The treatment being researched in my clinical trial has been proven to be the best treatment for my type of cancer.	Disagree$_{1*}$	Unsure$_2$	Agree$_3$
A10.	In my clinical trial, each group of patients receives a higher dose of the treatment than the group before, until some patients have serious side effects.	Disagree$_1$[**]	Unsure$_2$	Agree$_3$[††]
A11.	After I agreed to participate in my clinical trial, my treatment was chosen randomly (by chance) from two or more possibilities.	Disagree$_1$[‡‡]	Unsure$_2$	Agree$_3$[§§]
A12.	Compared with standard treatments for my type of cancer, my clinical trial does not carry any additional risks or discomforts.	Disagree$_{1*}$	Unsure$_2$	Agree$_3$
A13.	There may <u>not</u> be direct medical benefit to me from my participation in this clinical trial.	Disagree$_1$	Unsure$_2$	Agree$_{3*}$
A14.	By participating in this clinical trial, I am helping the researchers learn information that may benefit future cancer patients.	Disagree$_1$	Unsure$_2$	Agree$_{3*}$
A15.	Because I am participating in a clinical trial, it is possible that the study sponsor, various government agencies, or others who are not directly involved in my care could review my medical records.	Disagree$_1$	Unsure$_2$	Agree$_{3*}$
A16.	My doctors did not offer me any alternatives besides treatment in this clinical trial.	Disagree$_{1*}$	Unsure$_2$	Agree$_3$
A17.	The consent form I signed describes who will pay for treatment if I am injured or become ill as a result of participation in this clinical trial.	Disagree$_1$	Unsure$_2$	Agree$_{3*}$
A18.	The consent form I signed lists the name of the person (or persons) whom I should contact if I have any questions or concerns about the clinical trial.	Disagree$_1$	Unsure$_2$	Agree$_{3*}$
A19.	If I had not wanted to participate in this clinical trial, I could have declined to sign the consent form.	Disagree$_1$	Unsure$_2$	Agree$_{3*}$
A20.	I will have to remain in the clinical trial even if I decide someday that I want to withdraw.	Disagree$_{1*}$	Unsure$_2$	Agree$_3$

[*] Correct answer

[†] Scored for phase III subjects only

[‡] Scored for phase I subjects only

[§] Scored for phase II subjects only

[**] Correct answer for patients on phase II and III trials

[††] Correct answer for patients on phase I trials

[‡‡] Correct answer for patients on phase I and II trials

[§§] Correct answer for patients on phase III trials

APPENDIX: QUALITY OF INFORMED CONSENT (QuIC), PART B

When you signed the consent form to participate in your clinical trial, how well did you understand the following aspects of your clinical trial? *If you didn't understand the item at all, please circle 1. If you understood it very well, please circle 5. If you understand it somewhat, please circle a number between 1 and 5.*

		I Didn't Understand This at All		⇒		I Understood This Very Well
B1.	The fact that your treatment involves research	1	2	3	4	5
B2.	What the researchers are trying to find out in the clinical trial	1	2	3	4	5
B3.	How long you will be in the clinical trial	1	2	3	4	5
B4.	The treatments and procedures you will undergo	1	2	3	4	5
B5.	Which of these treatments and procedures are experimental	1	2	3	4	5
B6.	The possible risks and discomforts of participating in the clinical trial	1	2	3	4	5
B7.	The possible benefits to you of participating in the clinical trial	1	2	3	4	5
B8.	How your participation in this clinical trial may benefit future patients	1	2	3	4	5
B9.	The alternatives to participation in the clinical trial	1	2	3	4	5
B10.	The effect of the clinical trial on the confidentiality of your medical records	1	2	3	4	5
B11.	Who will pay for treatment if you are injured or become ill because of participation in this clinical trial	1	2	3	4	5
B12.	Whom you should contact if you have questions or concerns about the clinical trial	1	2	3	4	5
B13.	The fact that participation in the clinical trial is voluntary	1	2	3	4	5
B14.	Overall, how well did you understand your clinical trial when you signed the consent form?	1	2	3	4	5

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Further information about the NCI Comprehensive Working Group on Informed Consent is available at http://cancertrials.nci.nih.gov/researchers/safeguards/consent/recs.html.

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