Evaluating the quality of informed consent

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Context Although informed consent is a critical means of protecting the rights and interests of participants in clinical research, effective and efficient means of evaluating the quality of consent are needed. Having such means will be important to monitoring consent and testing potential improvements in the consent process.

Objective To develop and test a practical and general means of evaluating the quality of informed consent for clinical research.

Methods We developed and tested the Brief Informed Consent Evaluation Protocol (BICEP), a short telephone-based assessment of informed consent. As soon as patient-participants completed the informed consent process for a participating VA Cooperative Studies Program clinical trial they called an interviewer who administered the BICEP.

Results 632 participants completed BICEP, representing eight ongoing studies from 14 VA and one non-VA medical centers across the country. Site coordinators reported little to no difficulty implementing BICEP. The average duration of BICEP was 8.8 minutes (SD 3.6). Overall, patient-participants evaluated the informed consent process positively. A reliable coding system was then developed to analyze the verbatim responses of the final 191 participants. An Informed Consent Aggregate Score (ICAS) had a mean score of 8.23 (SD 1.17) with a range of 0–10, with 10 a perfect score; and a Therapeutic Misconception Aggregate Score (TMAS) had a mean of 1.62 (SD 0.93) with a range of 0–5, with 5 a perfect score.

Conclusions The BICEP is an efficient means of evaluating informed consent that is acceptable to research participants and research personnel. While participants tend to be satisfied with the informed consent process, the BICEP indicates there is room for improvement in the informed consent process for research.

Introduction

In the wake of the deaths of several research participants and the temporary closures of research programs at major academic institutions, the current mechanisms used to ensure protection of the rights and interests of those who participate in clinical research are under scrutiny [1–3]. Concerns have been raised about a number of issues including whether those engaged in designing, conducting, and overseeing research are adequately educated about the ethical issues inherent to research, whether Institutional Review Boards have adequate resources to conduct an appropriate review, and how conflicts of interest in the research manifest themselves [4–6]. Informed consent, an important protection in research, is also of concern. For example, the National Institute of Health has issued a call for research on informed consent and research ethics, and national groups highlight informed consent as part of their accreditation processes [7–10].

While informed consent is an important protection, federal regulations concerning informed consent
consent tend to focus on what information should be provided to potential research participants and be included in informed consent documents [11]. Nonetheless, for informed consent to meet the fundamental underlying goal of autonomous authorization, it is essential that investigators attend to whether the person being asked to give consent has adequate decision-making capacity (or competency) to give consent and is positioned to make a voluntary decision. In addition researchers must take care to provide not only comprehensive, but also understandable information about proposed research [12].

While there is a growing empirical database concerning such aspects of the informed consent process [13–15], much of the work published to date focuses on how much potential participants understand about the trial, typically specific information about its risks and potential benefits, leaving unaddressed other key ethical aspects of the informed consent process, such as the voluntariness of participation and whether participants understand the investigational nature of the research. One construct that has received substantial attention in the literature on informed consent is known as the “therapeutic misconception” [16]. The therapeutic misconception refers to the inaccurate belief on the part of participants in research that research procedures involve individualized treatments selected primarily for the benefit of the participants. Clearly, such a misconception threatens the validity of the informed consent process. Nevertheless, there is no consensus about how best to obtain and measure the quality of informed consent. The lack of measurement tools limits efforts to monitor and improve the process of obtaining valid informed consent. However, it is incumbent upon those engaged in clinical research and its oversight to develop and test such procedures [17].

To contribute to this task, we set out to develop, field-test, and validate an independent, real-time measure of the quality of informed consent encounters in actual clinical trials. Such a measure will facilitate assessing, monitoring, and ultimately improving the quality of informed consent for clinical research.

**Methods**

Recognizing that instrument development can be time and resource intensive, making it frequently impractical to develop study-specific evaluations of the quality of informed consent, we set out to develop and validate an instrument that could be used across different clinical trials. Unlike study specific instruments, a general instrument should be useful in a variety of clinical and research settings. In addition, we were interested in evaluating the quality of informed consent in terms of meeting the ethical goal of autonomous authorization described earlier, not simply measuring compliance with regulatory requirements for what needs to be disclosed to potential research participants.

We therefore assembled a small group of experts in ethics research, informed consent, and the oversight of clinical research to inform the development of an instrument to assess the quality of informed consent. As a result of the deliberations of this group, we set the following criteria: 1) the measurement process needed to be independent from the person who had obtained informed consent to minimize bias in the measurement process; 2) the results of the measurement should be kept confidential so that the person obtaining informed consent would be willing to be evaluated and that the privacy of the research participants would be respected; 3) to ensure that we were evaluating the informed consent process, and not changes of attitudes and beliefs based on experience in research, the evaluation should be done in real time; 4) the measurement should not interfere with important clinical and research activities; 5) the burden of completing the evaluation should be minimal for research staff and patient-participants; and 6) the method should be practical and simple.

Based upon these criteria we elected to conduct a telephone interview immediately following the completion of the informed consent process for a “parent” trial (an actual clinical trial that was actively enrolling patient-participants). In practice, this required the person who obtained informed consent for a parent trial to seek oral informed consent from each of the patient-participants to enroll in the informed consent study. Once consent was obtained and the patient-participant was in a private setting at the research site, such as an examination room or private office, the person who obtained consent contacted the project telephone bank. After the patient-participant was alone, a trained interviewer working under the supervision of one of the principal investigators (JS or PWL) confirmed consent to participate in the evaluation of informed consent and then conducted the interview we termed BICEP (Brief Informed Consent Evaluation Protocol). The interviewers hand-recorded the participants’ responses and verbatim comments. Soon after each BICEP interview was completed, site coordinators completed a form regarding the timing of the interview and their impressions of the process. These forms were faxed to the automated data entry system at the data center (Palo Alto Cooperative Studies Program Coordinating Center).

Coding of the verbatim responses was developed using standard qualitative data analytic methods. Specifically, a member of the project team who is
trained in anthropology reviewed the responses in their entirety for important themes. A syllabus of the terms that emerged along with a coding manual was refined based on input from the project team. Iterative reliability testing (inter-rater agreement studies) was employed to refine the manual. The results of this testing are described below.

Two summary scores were developed, the Informed Consent Aggregate Score (ICAS) and the Therapeutic Misconception Aggregate Score (TMAS). The components of these scores are described in Table 1. Closed-ended survey items were analyzed using standard descriptive statistics.

This project was reviewed and approved by the VA Palo Alto Cooperative Studies Program Coordinating Center’s Human Rights Committee, the Stanford University IRB, the Duke University Medical Center IRB, the Durham VA IRB and the IRBs at each of the participating sites.

Instrument development

The initial BICEP interview (BICEP I) was developed based on published empirical literature on informed consent [13,14] and advice from the expert advisory group. In developing the instrument, we set out to ensure that relevant components of the informed consent process were evaluated including the respondents’ impressions of the adequacy of the information provided, their understanding of the purpose of research, the benefits and risks of the research, the distinction between research and clinical care, voluntariness of participation, recall of signing a consent document, and satisfaction with the consent process. In drafting these items, we sought to make them applicable across different trials so that the same measurement instrument could be used without modification. That is, the items and/or their scoring did not focus on the specific details of particular protocols, but rather on the general aspects of informed consent. The BICEP-1 called for transcribing verbatim responses to structured queries. Following evaluation of the data gathered from the first 441 interviews we refined the survey instrument (BICEP-2), leaving most queries unchanged, but adding modules that called for interviewer coding of the verbatim responses into analyzable data. We then conducted the remaining 191 interviews.

The combination of structured queries and open verbatim responses in the BICEP-1 interviews made it possible to “mine” the 441 initial interviews both to revise queries and (most importantly) to develop coding procedures that would extract analyzable data from the responses. Most changes in the structured queries involved tightening language to clarify questions that proved ambiguous in practice. For example, in BICEP-1 we asked “What are the alternatives to participating in the [Parent Study]?” but the verbatim responses revealed that some respondents found the question confusing, so we rephrased it in BICEP-2 to read: “Suppose you had decided not to participate in [Parent Study], do you think that would have made any difference to your regular medical care?”. Some changes corrected misimpressions created by poorly phrased queries. For example, in BICEP-1 we asked “Did you have to sign a consent form to participate in [Parent Study]?” and in BICEP-2 we dropped the tenuous phrase “have” to from that query. We dropped the BICEP-1 query “Were you able to make a good decision about participating in [Parent Study]?” since it added nothing to the earlier question “Did you get all the information you needed to make a good decision about participating in [Parent

Table 1 Composition and percentage of respondents to components of aggregate scores

<table>
<thead>
<tr>
<th>ICAS: Informed Consent Aggregate Score</th>
<th>TMAS: Therapeutic Misconception Aggregate Score</th>
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<tbody>
<tr>
<td>Having all the information needed (92%)</td>
<td>Mentioning a direct benefit from participation (31%)</td>
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<tr>
<td>Recall of signing a consent form (99%)</td>
<td>Believing the research was ultimately directed at benefiting the self (6%)</td>
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<tr>
<td>Reporting no pressure (100%)</td>
<td>Not endorsing an aspirational benefit (36%)</td>
</tr>
<tr>
<td>Reporting no consequences to medical care of nonparticipation (95%)</td>
<td>Not reporting that the primary purpose of the parent study was to address a research question (11%)</td>
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<tr>
<td>Identifying an aspirational benefit (64%)</td>
<td>Not believing that the research was aimed at ultimately benefiting others (77%)</td>
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<tr>
<td>Being completely or somewhat satisfied with the informed consent process (99%)</td>
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<tr>
<td>Reporting that the study addresses a research question (89%)</td>
<td></td>
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<tr>
<td>Reporting that the research is directed at an outcome ultimately benefiting others (23%)</td>
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</tr>
<tr>
<td>Not reporting that the research was directed toward an outcome to ultimately benefit self (94%)</td>
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<tr>
<td>Showing clear appreciation that participation was voluntary (67%)</td>
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Where BICEP-1 simply recorded the verbatim responses to the questions “What are the benefits to you of participating in [Parent Study]?” and “What are the risks to you of participating in [Parent Study]?”, in BICEP-2 we added up to three prompts to increase the verbatim yield on the queries and kept track of the total time used by the research volunteer in describing benefits and risks. We also added a coding section for the interviewer to record whether the benefits described were general or specific, and for specific benefits to count up the numbers of responses specified categories direct, indirect, aspirational, and “unable to categorize”. Similarly, for risks we added coding for numbers of risks in specified categories physical, psychological, social, economic, and “unable to categorize”. As a result of analysis of the purely verbatim responses to the query “What is the primary purpose of [Parent Study]?”, we added a coding section that characterized responses according to the categories “Addresses a research question”, “Directed at an outcome to ultimately benefit others”, “Directed at an outcome to ultimately benefit self”, and “Other”. In BICEP-1 the query “When can you stop participating in [Parent Study]?” proved to be ambiguous, with verbatim responses indicating that some research volunteers interpreted the query as “Can you tell me when the [Parent Study] ends?”, so we added that query before the “stop participating” query to separate the concepts.

In a final revision of the instrument at the end of the study we added an item to record whether the parent study coordinator obtained informed consent to participate in EQUIC before or after the parent study informed consent process. We also added coding to capture whether the respondent indicated any uncertainty in answering the question “Did you sign a consent form to participate in [Parent Study]?” and coding for whether the respondent expressed a consistent or inconsistent response to the query “Did you feel any pressure to participate in [Parent Study]?” Finally, we added a section coding the respondent to the query about “stopping participation” to reflect whether the respondent showed a clear appreciation of voluntariness, and if not, what reasons for stopping were cited. All of the above coding was also performed retrospectively on the BICEP-1 and -2 responses, but in the revised final BICEP-3 (Appendix) the coding sections are included “in line” with the queries and meant to be completed during or shortly after the interview.

Results

Between 21 August 2000 and 2 July 2002, 632 patient-participants completed the BICEP (441 completed BICEP-1 before 31 July 2001; 191 subsequently completed BICEP-2). Five patient-participants giving consent to a parent study refused the BICEP interview. Nevertheless, because site coordinators were not required to log those patients who had enrolled in a parent study along with whether they were approached and agreed to participate in our evaluation of informed consent, it is possible that the number of refusals is underestimated. The mean age of participants was 67 (SD 7.2), 74% were male, 72% had some college education, 93% were white, 4% black, and 3% other. Participants were from one of 14 different VA medical centers and one non-VA medical center, and were enrolled in one of eight “parent” studies. The sites were located across the USA: Ann Arbor, MI; Birmingham, AL; Buffalo, NY; Durham, NC; Houston, TX; Indianapolis, IN; Lexington, KY; Rochester, MN (Mayo Clinic); Melbourne, FL; Minneapolis, MN; Northport, NY; Reno, NV; Seattle, WA; and St. Louis, MO. The parent studies involved the evaluation of both treatments and prevention and are described in Table 2.

Table 2  Participating parent trials

<table>
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<tr>
<th>Trial N (%)</th>
<th>Description</th>
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<tr>
<td>FDG PET 8 (1)</td>
<td>Accuracy of F-fluorodeoxyglucose positron emission tomography compared to CT scan and chest X-ray to distinguish benign and malignant solitary pulmonary nodules</td>
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<tr>
<td>Shingles vaccine 417 (66)</td>
<td>Randomized comparison of varicella zoster vaccine versus placebo for prevention of shingles</td>
</tr>
<tr>
<td>FeAST 11 (2)</td>
<td>Randomized trial evaluating whether lowering blood iron levels by phlebotomy can reduce mortality in patients with peripheral vascular disease</td>
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<tr>
<td>COURAGE 17 (3)</td>
<td>Randomized trial evaluating whether the addition of optimal catheter-based coronary revascularization to medical therapy can reduce all cause mortality and nonfatal MI in patients with chronic angina, uncomplicated MI, asymptomatic myocardial ischemia, or coronary artery disease</td>
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<tr>
<td>HOST 11 (2)</td>
<td>Randomized survival trial of vitamin supplements for reduction of homocysteine levels in patients with renal failure</td>
</tr>
<tr>
<td>PTSD in women 5 (1)</td>
<td>Randomized trial of an exposure therapy for women veterans with service-connected post-traumatic stress disorder resulting from sexual trauma</td>
</tr>
<tr>
<td>SELECT RCT: 127 (20); cohort: 36 (6)</td>
<td>Randomized trial of selenium and vitamin E for the prevention of prostate cancer; and latent prostate (a prospective cohort study of early stage prostate cancer)</td>
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The BICEP was well-tolerated by staff and patients. According to the persons who obtained consent for the parent studies, 98.9% had no difficulty with the process; 99.5% had no difficulty finding a place to make the call; 95.4% had no difficulty reaching the center; and 98.4% had no interruption of clinic flow. In addition, 66.3% reported no disruption of the parent study, while 32.8% reported only mild disruption.

The average time between obtaining informed consent for the parent trial and obtaining oral consent for BICEP was 19.8 minutes (std dev 28.0 m, quartiles 4.20). The average time between obtaining consent for EQUIC and initiating the call was 8.4 m (std dev 11.7 m, quartiles 2.10). The average duration of the call was 7.7 m (std dev 2.9, quartiles 6.9).

Respondents had very favorable reports about the informed consent process for the parent studies. 95.1% reported the amount of information received was “just right”; 99.3% remember signing the consent form; 99.8% felt no pressure to consent; 98.4% felt they made a good decision to participate; 89.1% were completely satisfied with the informed consent process and 9.0% were somewhat satisfied.

The verbatim responses to selected interview items present a somewhat more complete picture of the informed consent process. To assess whether respondents understood that the parent studies involved research, they were asked, “What is the primary purpose of [parent study]?” Coded verbatim responses to this item show that 80% of the patients understood that the parent study addressed a research question and 59% volunteered that the parent study is directed at an outcome ultimately to benefit others. However, 6% mentioned that the parent study was directed at an outcome ultimately to benefit themselves, and 1% mentioned some other purpose.

Benefits to participation in research can be understood to include “direct benefits” (those benefits directly related to the intervention being tested); “indirect benefits” (also known as “collateral benefits” that accrue simply by being a research participant, such as closer monitoring); and “aspirational benefits” (the ultimate benefits of research in terms of knowledge gained) [18].

While the nature of the trial influences whether direct or indirect benefits are reasonably expected, all research should have aspirational benefits. To help assess the extent to which the nature and range of benefits of participation that were understood, verbatim responses to the question, “What are the benefits to you of participating in [parent study]?”, were coded according to type of benefit. Patients indicated at least one direct benefit 50% of the time, indirect benefits 62% of the time, and aspirational benefits 47% of the time. To help assess in part the voluntariness of continued participation, respondents were asked “When can you stop participating in the [parent study]?”. Verbatim responses to this item were coded according to whether there was a clear understanding of voluntariness; 55% had a clear understanding.

To test the reliability of the coding system, we had three raters independently code the responses from the 42 respondents who were participating in the randomized trials (out of the 191 in the second phase of the study) that were testing therapies (in contrast to those testing preventive measures). We constructed the subscore of the ICAS corresponding to the coded items, and calculated an intraclass correlation coefficient (ICC) of 0.75. The ICC is the ratio of subject variance (0.94) to total variance (1.25). Since the non-coded (direct response) ICAS items would add to the subject variance but would not vary across coders (in a fixed-format structured interview), the true ICC for the ICAS would be expected to be somewhat higher. Estimating the reliability of the non-coded items would require an unrealistic test-retest design, infeasible in the context of informed consent.

To have a comprehensive measure of the quality of informed consent, we constructed an Informed Consent Aggregate Score (ICAS), comprised a priori of 10 responses (closed-ended or coded) that provided important information about the quality of consent (See Table 1). Each item was scored 1 for Yes and 0 for No, and then the aggregate score was the sum. The mean ICAS was 8.23 (std dev 1.17, quartiles 8,9), out of a possible range of 0–10, with 10 a perfect score; while five of 191 (2.6%) had scores of 5 or less.

To assess the presence of a therapeutic misconception, we constructed a Therapeutic Misconception Aggregate Score (TMAS) from five response items selected a priori (see Table 1). Each item was scored 1 if Yes and 0 if No, and then the aggregate score was the sum. The mean TMAS was 1.62 (std dev 0.93) with a possible range of 0–5; 0 = no misconception, and nine of 191 (4.7%) of patient-participants scored 4 or 5. As might be expected the ICAS and the TMAS were inversely correlated (Pearson correlation coefficient −0.73).

Discussion

Although there is substantial research on the informed consent process underway [19,20], our work reflects what is perhaps the largest reported empirical evaluation of a measure of the quality of the consent process for research. In over 600 interviews with patients who had given consent to participate in clinical trials, the BICEP is well tolerated and imposes minimal burden on research participants and staff. In addition, the measures we
developed are reliable and seem to have face validity in terms of the underlying ethical goal of obtaining autonomous authorization in the informed consent process. Thus, independent telephone evaluations of the quality of informed consent are feasible. Furthermore, our data indicate that there is room to improve the consent process. Of special concern is the voluntariness of continued participation and that participation has a research purpose aside from whatever personal benefits might result. Such will be the focus of our future work.

Despite the large, multicenter, and nationwide sample used in this study, our findings should be interpreted with a few limitations in mind. First, BICEP completers may have been a selected subsample of parent-study participants, as study coordinators did not adhere consistently to the protocol calling for all parent-study participants to be approached. In addition, the high rate of agreement to participate in the BICEP interview may depend on the fact that the person who obtained consent for the parent-study also obtained consent for the BICEP. Further, many of the participants in this research were enrolled in parent studies aimed at evaluating preventive interventions, rather than therapies. Accordingly, the responses of those enrolled in trials evaluating treatments might differ. The small number of nonwhite participants does not reflect the usual distribution of minority patients in VA research, nor the US population. The VA Cooperative Studies Program also coordinated all of the parent studies from which we recruited participants for BICEP and therefore the results may not be generalizable to studies coordinated by others such as academic medical centers or industry. However, given the great similarities in the way that large, multicenter trials are organized and coordinated, we believe it is unlikely that the differences would be great. It is also conceivable that the BICEP might work differently in a population without such a high prevalence of veterans. Accordingly, we are exploring the possibility of testing the BICEP in other settings.

Testing the BICEP in other settings will also make it possible to see if the BICEP can be adapted for use in monitoring the informed consent process. Such a modality promises to add a crucial element of direct measurement to other monitoring approaches such as auditing files to ensure completion of the consent documents or a content review of these documents. Of course, using the BICEP for such purposes raises questions about the funding for this purpose and the authority of the monitors in comparison to the clinical research staff who obtained informed consent for the parent studies.

Nonetheless, other methods such as intensive interviewing and actual observation of the informed consent process might promise a more robust evaluation. However, both approaches may themselves be a substantial intervention in the consent process, require a substantial investment of time and resources, and may not be sustainable. For example, Appelbaum and colleagues have developed an instrument, the McAT-CR that focuses on the competency of persons to consent to specific clinical research trials [21]. Kodish and colleagues have videotaped the informed consent process, analyzed these encounters and interviewed participants following the encounter [22] yet there is little evidence to suggest what criteria should be used in assessing these observations. Despite the apparent limitations of such approaches to application in actual research settings, comparing the findings obtained using these approaches to the BICEP would help further assess the validity of the BICEP. Nevertheless, the BICEP provides an enlarging background of data upon which to understand the quality of informed consent that would likely be unaffected by the measurement process itself.

As attention is appropriately focused on ensuring that the rights and interests of those enrolled in clinical research are protected, it is essential to inform these conceptual and policy efforts with relevant empirical data. When it comes to ensuring that informed consent is meaningful, these sorts of data are especially pertinent and obtainable.

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References


Appendix

EQUIC CSP#476 BICEP

Before the EQUIC interview begins, the interviewer speaks with the site coordinator or assessment technician to collect the parent study information, the patient ID number, and time that informed consent for EQUIC was obtained. Once the patient is on the phone with the interviewer, the following dialog begins and the interviewer uses his/her best effort to use the subject’s own words. If needed, the interviewer may include a comment on the BICEP for clarification of the subject’s response.

EQUIC Interview

“Hello, my name is ___. I work for the VA. Thank you for agreeing to participate in our study called EQUIC-SM, which stands for Enhancing the Quality of Informed Consent-Self Monitoring phase. I understand that you have just agreed to join another research project called [Parent Study], is that correct?”

If NO, interviewer needs to seek clarification from research staff of the parent study.

If YES, then proceed: “I would now like to ask you some questions about when you gave informed consent to participate in [Parent Study] and what you understand about participating in that study. Sound okay?”

If NO, interviewer needs to seek clarification from research staff of the parent study.

If YES, then proceed:
1) “Did you get all the information you needed to make a good decision about participating in [Parent
Study]? Was it... too much; just right; too little?” The interviewer has the option to label the answer as “unable to code” and include a comment for clarification of the subject’s response and reason for the coding choice.

2) “Did you sign a consent form to participate in [Parent Study]?” If the answer is “no”, the project manager is notified and contacts the sites to discuss the subject’s response and take corrective action if needed. The interviewer looks for any indication of uncertainty in the subject’s response and makes note of it.

3) “Did you feel any pressure to participate in [Parent Study]?” The interviewer marks “Yes”, “No”, or “Not sure” and records the verbatim response.

4) “Suppose that you had decided not to participate in [Parent Study], do you think that would have made any difference to your regular medical care?” Interviewer records “Yes”, “No”, or “Not Sure” and verbatim response.

5) “What are the benefits to you for participating in [Parent Study]?” Depending on the subject’s response, one of the following prompts is used: “Can you think of any benefits?”, “Can you tell me what those benefits are OR Can you tell me what the benefit is?”, or “Can you think of anything else?” The time it takes for the subject to answer the question is recorded. The interviewer must choose the most accurate response category about the benefits, which include: Direct, Indirect, Aspirational, Unable to Categorize.

6) “What are the risks to you for participating in [Parent Study]?” Again, depending on the subject’s response, one of the following prompts is used: “Can you think of any risks?”, “Can you tell me what those risks are OR Can you tell me what the risk is?”, or “Can you think of anything else?” The time it takes for the subject to answer the question is recorded. The interviewer must choose the most accurate response category about the risks, which include: Physical, Psychological, Social, Economic, or Unable to Categorize.

7) “Were you satisfied with the informed consent process?” Along with a verbatim response, the interviewer rates the subject’s level of satisfaction as either completely satisfied, somewhat satisfied, somewhat dissatisfied, or dissatisfied.

8) “As a result of participating in [Parent Study], what are the main things you will have to do differently than if you were not participating?” Verbatim recorded.

9) “What is the primary purpose of [Parent Study]?” The interviewer uses the verbatim response to determine if the subject addresses a research question, an outcome that benefits other, an outcome that benefits them, or another unique response.

10) “Can you tell me when the [Parent Study] ends?” Verbatim recorded.

11) “When can you stop participating in the [Parent Study]?” Verbatim recorded. The interviewer listens to the subject’s response to identify that he/she has a clear understanding that their participation in the parent study is voluntary. If the subject replies with a comment that does not indicate this understanding, the reason for their commitment to the study is recorded.

12) “I have been trying to learn about your impressions of the informed consent process for [Parent Study]. Is there anything else you would like to tell me about?” If the subject has any other comments, they are recorded.