Published in final edited form as:
Cancer. 2010 July 1; 116(13): 3244–3250. doi:10.1002/cncr.25158.

Informed Consent for Pediatric Phase I Cancer Trials: Physicians' Perspectives

Tsiao Yi Yap[1], **Amy D. Yamokoski**[2], **Sabahat Hizlan**[2], **Stephen J. Zyzanski**[3], **Anne L. Angiolillo**[4], **Susan R. Rheingold**[5], **Justin N. Baker**[6], **Eric D. Kodish**[2], and **on behalf of the Phase I Informed Consent (POIC) research team**

[1] Department of Pediatric Hematology/Oncology and Bioethics, Children's Hospital, Cleveland Clinic, Cleveland, Ohio

[2]Department of Bioethics, Cleveland Clinic, Cleveland, Ohio

[3]Department of Family Medicine, Case Western Reserve University, Cleveland, Ohio

[4]Division of Oncology, Center for Cancer and Blood Disorders, Children's National Medical Center, Washington, D.C.

[5]Division of Oncology, Children's Hospital of Philadelphia, Philadelphia, PA

[6]Division of Palliative and End of Life Care, St. Jude Children's Research Hospital, Memphis, TN

Abstract

Background—This study was conducted in order to gather pediatric oncologists' opinions about and suggestions for improvement of informed consent in pediatric phase I cancer trials.

Methods—A questionnaire designed to elicit perspectives was distributed to 146 physicians at six participating institutions. One hundred three completed surveys were returned for a 71% response rate.

Results—Pediatric oncologists believe providing information so families can decide about phase I study entry is the most important goal of the informed consent process (ICP);. Most physicians (64%) report that they describe the phase I study without any attempt to influence parents' decisions. A number of answers provided by physicians were associated with their gender and prior informed consent training,. Male physicians were significantly more likely to endorse the "no attempt to influence" approach, whereas female physicians were more likely to suggest to parents that *other* children will benefit from what is learned in phase I studies. Responses to an open-ended question provided 63 suggestions for improvement of the ICP, including document and training changes and tools to enhance physician-family communication.

Discussion—We found that pediatric oncologists tend to present phase I trials as an option rather than a strong recommendation and feel reluctant to influence decisions of families about these studies. They believe most but not all parents understand key concepts involved in consent to this type of research, and had ample suggestions for how to improve the ICP. Future research and education efforts around this ethically challenging topic are warranted.

Keywords

informed consent; pediatric oncology; phase I trials; ethics; physicians' perspectives

Corresponding author: Eric D. Kodish, MD Department of Bioethics Cleveland Clinic 9500 Euclid Avenue JJ60 Cleveland, OH 44195 Phone: (216) 444-3850 Fax: (216) 444-9275 kodishe@ccf.org.

INTRODUCTION

Phase I trials are critical for the development of new anti-cancer therapies. The traditional goal of phase I trials is to determine maximum tolerated dose (MTD) and dose limiting toxicity (DLT) of a new agent and establish an appropriate dose for use in subsequent phase II trials.[1] Phase I trials are considered for children with refractory tumors when conventional therapies have proven ineffective and cure is unlikely. There will always need to be a "first-time" a drug is used in humans, and waiting until the new agent has been exhaustively studied in adults will slow progress against childhood cancer. Assuring early pediatric access to such therapies will require a fuller understanding of the balance between protection from risk and the potential for benefit. Along with the need to gather pediatric-specific data to inform the rational use of each new agent comes an equally compelling responsibility to obtain meaningful informed consent.

Informed consent is the process by which decision making about phase I trial participation takes place. In pediatrics, informed consent is comprised of parental permission and assent of older children.[2] Communication and decision-making in the phase I context are fraught with difficulties for both physicians and patients. Some are concerned that the severity of the disease and poor prognosis inherent in the phase I context can increase the vulnerability of patients and their families, confounding the already difficult task of obtaining truly informed consent. [3,4] Families are confronted with difficult decisions in weighing the risks and benefits of participating in phase I trials while considering other options, including hospice/palliative care programs.[5] Physicians often report a tension between providing a truthful prognosis and presenting experimental drug options while still maintaining hope for the family.[6,7,8,9] They may also experience role conflict between obligations to advance medical science for the benefit of future patients and the best interests needs of the child who is a potential research subject.[10] Furthermore, given the sparse data on how decision-making transpires during these stressful times, physicians are left with little guidance. These concerns demonstrate the need for research about the communication that takes place around decisions regarding pediatric phase I cancer studies.[10]

In this paper, we present data about the experience and opinions of pediatric oncologists with the informed consent process (ICP) for phase I childhood cancer trials. The goal of the study is to better understand the ICP from the perspective of those who are expected to communicate in this challenging context. We set out to discover perceived goals of and obstacles to good informed consent, and to identify physician beliefs about parental comprehension of various aspects of phase I trials. Finally, we hoped to learn what suggestions doctors might have to improve the ICP.

METHODS

Results discussed in this paper are a component of a larger ongoing multi-site study, the Phase I (One) Informed Consent (POIC) project, designed to understand communication between physicians and families, as well as comprehension, and decision-making of parents and older child-patients. The six pediatric cancer phase I centers participating include St. Jude Children's Research Hospital, Memphis, TN; Children's Hospital of Philadelphia, Philadelphia, PA; Children's Hospital Pittsburgh, Pittsburgh, PA; National Cancer Institute-Pediatric Oncology Branch, Bethesda, MA; Children's National Medical Center, Washington, DC and Children's Hospital and Regional Medical Center, Seattle, WA. This study was approved by IRB(s) at each data collection site and at Cleveland Clinic, Cleveland, OH (administrative home). Site co-investigators, along with research associates (RA), identified attending physicians and fellows who would potentially conduct phase I informed consent conferences at their individual sites. Once the 146 physicians were

identified, the study was introduced to these pediatric oncologists and the instrument was administered. Data collection began in February 2008 and ended in December 2008.

The instrument was originally developed for a pilot study surveying both physicians and parents involved in informed consent for pediatric cancer clinical trials.[11] It was subsequently modified for use in a larger study designed to understand the ICP for phase III leukemia trials at five major institutions across the United States.[12] The current instrument was then modified for use in the context of informed consent for phase I pediatric cancer trials. It consists of 25 items and is available upon request from the corresponding author. Although this specific questionnaire was not pilot tested within the phase I context, we believe it to be a valid and reliable instrument based on our previous experiences with the original instrument as stated above.

Statistical considerations

Quantitative responses were analyzed using SPSS 14.0. We computed aggregate data for all variables based on the 103 total sample. Categorical associations between physician gender and type of IC training and other categorical variables within the questionnaire were assessed by means of chi square statistics. Significant associations among continuous variables were tested by means of Pearson correlations. Linear regression analysis was also performed on selected outcomes in order to identify major independent predictors for each.

Physician responses to the open-ended question, “How do you think we can make the Phase I informed consent process better?” were transcribed and responses were then independently categorized into eight themes by two of the manuscript's authors (TY and AY) using semantic content analysis.[13,14] Categorized data were ranked according to frequency of suggestions in each category.

RESULTS

Demographic Data

One hundred three completed surveys were returned for a response rate of 71%. Eighty-one percent of study participants were attending physicians and 19% were fellows in training (Table 1). The majority of participants were White, and there was an equal distribution of male and female physicians. When asked the question “How did you learn to discuss informed consent in pediatric cancer research?” the instrument provided two options: “A formal training program” and “Informal training through observation of mentors” and instructions to “check all that apply.” Most physicians (79%) who completed our survey selected informal training only.

Goals of Informed Consent Process

When asked to rank the most important goals of the ICP, physicians reported that providing information so families can decide about study entry (49%, 50 of 103) and explaining the progression of the disease and its treatment options (32%, 33 of 103) are the two highest priorities. Fourteen of 103 physicians (14%) viewed protection of the rights of subjects as the most important goal, while only 3 (3%) ranked documenting the review of risks and benefits and 2 (2%) selected protecting children from research-related risks as the most important goal. Those who selected explaining progression of disease as the most important goal were more likely to have received only informal informed consent training (Table 2, $p<0.05$). Female physicians were more likely than male physicians to believe that providing information so families can decide about study entry is the most important goal of the ICP (Table 3, $p< 0.029$).

Approach to Informed Consent

We asked our respondents to endorse from a list of four choices the one statement that best describes the way they approach informed consent discussions. Most pediatric oncologists reported that they describe the phase I study without any attempt to influence parents' decisions (64%, 63 of 99). Thirty percent (30 of 99) reported that they tell families about the phase I study and suggest that *other* children will benefit from what is learned in the study. Six of 99 (6%) endorsed the approach of recommending that the child go on the phase I study. No respondents selected the option where they suggest that *the child* will benefit directly from participation. Further analysis revealed male physicians were more likely to report that they describe the phase I study without any attempt to influence parental decision-making, whereas female physicians reported a tendency to suggest that *other* children will benefit from what is learned in the study (Table 3, $p<0.052$).

The instrument contained a five point Likert scale asking "How directive are you when you recommend a Phase I study?" with "very directive" as a 1 and "non-directive" as a 5 at the two poles of the scale. Forty-eight percent (48 of 99) responded that they were non-directive, and an additional thirty-nine percent (39 of 99) of physicians circled the midpoint on the scale. None of the 99 respondents to this item circled the "very directive" response.

Physicians were asked to specify the youngest age at which a child should be included in a *discussion* about participation in phase I research. The mean age at which pediatric oncologists believed a child should be included in an informed consent *discussion* was 10 (range 3 to 16). Physicians were then asked to specify the youngest age at which a child should be involved in *making a decision* about participation in phase I research. The mean age at which pediatric oncologists reported a child should be involved *in making a decision* about participation in phase I research was 12 (range 5-18).

Therapeutic/Medical Benefit

When asked, "Do you believe that current patients receive direct therapeutic/medical benefit from participation in Phase I studies?," 58 of 96 physicians (60%) answered "yes" to this item, and the remaining 40% said "no." In the absence of a quantitative qualifier for this question, approximately 15 percent of the 58 answering "yes" to this question commented in the survey's margin that in reality only a small percentage of patients will directly benefit from phase I trial participation.

Perceived Parental Comprehension, Decision Making and Impact of the ICP

Parental comprehension of the rights of a research subject, design and goals of a research trial are key endpoints for the ICP. In this study, we asked physicians to make percentage estimates of parents who understand a variety of concepts related to phase I research protocols at the time they decide whether to enroll their child on the study. On average, pediatric oncologists thought that about half of parents [51% (SD 24)] understand "dose escalation" and about 40% (SD 23) of parents understand that their child will be unlikely to receive direct therapeutic/medical benefit from participating. Pediatric oncologists thought about three quarters of parents understood the meaning of "toxicity" (73%; SD 22), their right to withdraw from study (82%; SD 20), that data collected about their child would be handled confidentially (81%; SD 20) and they can choose other options for care, such as palliative treatment, comfort care or hospice (73%; SD 24).

When asked about who usually makes the decision about whether a *young* child (<14) with cancer enters a phase I study, physicians reported that parent(s) almost always (98%, 99 of 101) make the decision. When asked about who usually makes this decision for an *older* child (>14) with cancer, 73% (74 of 102) still stated that the child's parent(s) makes the

decision, while 26% of physicians believed the child him/herself makes the decision about study entry.

When asked to assess the emotional impact of the phase I ICP on parents based on their observations, pediatric oncologists most often reported that the ICP usually makes parents feel more in control of the situation (45%, 46 of 101) but that the process makes parents feel more anxious (47%, 48 of 101).

Obstacles to Good Informed Consent

Respondents were asked to rank order a list of five possible obstacles to good informed consent.[12] The two answers most commonly chosen by physicians as the greatest obstacles to good informed consent were, “Parents’ eagerness to “try anything” after a relapse/ refractory diagnosis” (34%; 33 of 98) and “Maintaining hope for the parents/patient while providing accurate, honest information about the child's condition” (34%; 33 of 98). An additional 20% (20 of 98) of physicians reported “the length of and language used in the consent document” as the greatest obstacle to good informed consent. The complexity of phase I study designs and requirements mandated by the Institutional Review Board were selected by only 10% and 3%, respectively.

Factors associated with physicians’ opinions

Our analyses showed that physician gender and type of prior informed consent training may influence their approach to the ICP. For ease of comparison, Tables 2 to 3 itemize self-reported opinions of our subjects based on physician characteristics mentioned above.

Pediatric oncologists in this sample who had some formal consent training (Table 2, $p \leq 0.004$), tended to report that the ICP usually makes parents feel more anxious and less in control of the situation. Similarly, female physicians (Table 3, $p \leq 0.008$) believed parents are more likely to feel anxious after the ICP. More female (Table 3, $p \leq 0.03$) physicians reported that they are directive when recommending a phase I study compared to their male counterparts.

Physicians’ Suggestions

The survey's final open-ended question elicited suggestions from physicians about how to make the phase I ICP better. Out of 103 physicians who completed surveys, 46 provided an answer to this question (response rate of 45%). Cumulative answers yielded a total of 63 suggestions, which were grouped into eight different categories (Table 4). These eight categories were further collapsed into four overriding themes: (1) issues with the overall ICP and document, (2) role of physicians and other health care professionals (HCPs), (3) improvements in communication for families, and (4) other/regulatory issues.

The most frequently cited suggestion related to content of the informed consent document (29%). Twenty-eight percent of physician suggestions centered around roles of the pediatric oncologist and HCPs during the ICP. Sixteen percent suggested a formal training program focused on effective communication. Specific ways physicians suggested for improving communication included “spending more time” and “increasing transparency.”

Coders agreed that two open-ended responses did not fall into any category named above. These were considered: “other/regulatory”; one suggested “simplifying the study entry process” while the other pertained to the problematic “requirement by the IRB to review the consent document verbatim.”

DISCUSSION

One key to understanding and ultimately improving the quality of IC is to better understand the views of physicians at the nexus of investigational medicine and clinical care. This study provides data to enrich that understanding. We found that pediatric oncologists tend to present phase I trials as an option rather than a strong recommendation and feel reluctant to influence decisions of families about these studies. They may share therapeutic optimism with patients and families but are also realistic about the prospect of medical benefit. They believe most but not all parents understand key concepts involved in consent to this type of research, and had ample suggestions for how to improve the ICP.

Estlin et. al conducted a study to determine perceptions of pediatricians on phase I trials more than a decade ago.[15] They surveyed 53 physicians from the United Kingdom Children's Cancer Study Group (UKCCSG) and 78 from the former Pediatric Oncology Group (POG). In contrast to our specific focus on informed consent, the Estlin study covered a range of ethical topics including physicians' perspectives of the challenges associated with phase I trials, perceived reasons for enrolling a child onto phase I trials and opinions about benefits and risks of participating in these trials. They then contrasted and compared the responses of American and British physicians. Similar to our findings, most physicians in the Estlin et al. study believed that patients receive some form of medical benefit from participating in phase I trials. [15] Results presented here complement this previous research.

Physicians viewed the goal of providing information to families as the highest priority for the phase I ICP. In our study, pediatric oncologists did not appear to encourage or strongly recommend these trials, but rather it appears that they tend to emphasize a more neutral framework. Approaches described by "no attempt to influence their decision" and "suggesting that **other** (*bold in original instrument*) children will benefit" were endorsed by 93 out of 99 respondents. They considered the two most formidable obstacles to good informed consent to be 1) parents' eagerness to "try anything" after a relapse/refractory diagnosis for their child and 2) maintaining hope for the parents/patient while providing accurate, honest information about the child's condition. Previous studies have indicated that patients often enroll in phase I trials at least partially because of hope for cure .[15, 16, 17] In this way our findings are compatible with previous results in both adult and pediatric contexts.

Male physicians were significantly more likely to endorse the "no attempt to influence" approach, whereas female physicians were more likely to suggest to parents that *other* children will benefit from what is learned in phase I studies. A substantial body of work in feminist ethics suggests emphasis on relationships and responsibility can help to reframe the more traditional understanding of morality.[18, 19] The fact that female physicians approach the ICP in a manner more connected to this way of thinking supports further conceptual and empirical investigation. Pure neutrality may not be the right approach to pediatric phase I consent, and benefits that may accrue to other children is certainly worthy of attention.

Assent is another very challenging component of the ICP. In our previous research, physicians reported mean ages of 11 and 13 years as the youngest ages child-patients should be included in a *discussion* of IC and involved in *decision making* about participation in phase III oncology trials, respectively.[11] Physicians from the current study reported the mean youngest age for a child to be included in a *discussion* of IC and involved in *decision making* about participation in phase I trials as 10 and 12 years, respectively. One potential reason for this difference in ages is the nature of phase I trials when compared to phase III trials. Often, children who are approached to participate in phase I trials have experienced

prior therapy and/or have participated in phase II or III research and may indeed have a better understanding of the concept of clinical studies. Physicians' knowledge that a phase I trial is unlikely to result in direct medical benefit to participants, but rather aid in scientific advancement for pediatric cancer more generally, may also factor into a decision to include child-patients in discussions and decisions about phase I trials at younger ages. Interviews with older children and teenager participants in the ICP, which highlight their opinions and preferences, could provide a critical perspective in future research.

The issue of therapeutic misconception in phase I trials continues to spark ethical debate. Although 60% of surveyed physicians believe patients receive therapeutic/medical benefit from trial participation, 15% amongst this group annotated on the survey's margins that *only a small percentage* of patients do actually benefit from phase I studies. Results from this item indicate that physicians are realistic about potential therapeutic benefits of phase I trials but at the same time reveal therapeutic optimism[20] and hope for patients who are phase I candidates.

Limitations of this study include the fact that the sample was drawn from only six of 20 centers in the Children's Oncology Group Developmental Therapeutics Consortium conducting phase I trials, and lack of real-time information about the ICP. The results reported here may not generalize to smaller centers with less experience. Ongoing research based in direct observation and recording of phase I ICPs followed by interviews with patients and parents and case-specific responses from physicians will help to fill the gap.

Future research should examine perspectives of older child-patients considering phase I trials. Detailed qualitative research focused on interactions between physicians, parents and patients may offer more specific suggestions to help improve this process. Educational efforts around this topic that include both physicians and families are essential to improving informed consent in phase I pediatric cancer trials for all stakeholders—physicians, parents, and child-patients.

Condensed Abstract

One key to understanding and ultimately improving the quality of informed consent for pediatric phase I cancer trials is to better understand the views of pediatric oncologists at the nexus of investigational medicine and clinical care. Gaining insights into physicians' experiences with, and opinions of, the informed consent process in this sensitive context enhances future research and education efforts around this ethically challenging topic.

Acknowledgments

The authors would like to thank members of the POIC Research Team and all research staff and physicians who participated in this study. We want to acknowledge Ariane Mitchum for her assistance with assembly of data. This work was supported by the NIH via the National Cancer Institute (NCI) and the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) (1RO1CA122217).

Authors' financial disclosures: Susan Rheingold, MD: Research funding from the Leukemia and Lymphoma Society for a Translational Research Grant (for a phase I drug trial). There are no other financial disclosures to report.

References

1. Smith M, Bernstein M, Bleyer WA, Borsi JD, Ho P, Lewis IJ, et al. Conduct of phase I trials in children with cancer. J Clin Oncol. Mar; 1998 16(3):966–78. [PubMed: 9508179]

2. Kodish E. Informed consent for pediatric research: Is it really possible? J Pediatr. Feb.2003 142:89–90. [PubMed: 12584521]
3. Daugherty CK, Banik DM, Janish L, Ratain MJ. Quantitative analysis of ethical issues in phase I trials: A survey interview study of 144 advanced cancer patients. IRB. 2000; 22(3):6–14. [PubMed: 11697385]
4. Oberman M, Frader J. Dying children and medical research: access to clinical trials as benefit and burden. Am J. Law Med. 2003; 29(2-3):301–17. [PubMed: 12961809]
5. Hinds PS, Pritchard M, Harper J. End-of-life research as a priority for pediatric oncology. J Pediatr Oncol Nurs. May-Jun; 2004 21(3):175–9. [PubMed: 15296049]
6. Gordon EJ, Daugherty CK. 'Hitting you over the head': Oncologists' disclosure of prognosis to advanced cancer patients. Bioethics. Apr; 2003 17(2):142–68. [PubMed: 12812182]
7. Kodish E, Post SG. Oncology and hope. J Clin Oncol. Jul.1995 13(7):1817. [PubMed: 7602370]
8. Miller M. Phase I cancer trials. A collusion of misunderstanding. Hastings Cent Rep. Jul-Aug; 2000 30(4):34–43. [PubMed: 10971892]
9. Groopman JE. A strategy for hope: a commentary on necessary collusion. J Clin Oncol. 2005; 23(13):3151–2. [PubMed: 15860877]
10. Kodish E. Pediatric ethics and early-phase childhood cancer research: Conflicted goals and the prospect of benefit. Account Res. 2003; 10:17–25. [PubMed: 14552299]
11. Kodish ED, Pentz RD, Noll RB, Ruccione K, Buckley J, Lange BJ. Informed consent in the children's cancer group: Results of preliminary research. Cancer. Jun 15; 1998 82(12):2467–81. [PubMed: 9635541]
12. Simon C, Eder M, Raiz P, Zyzanski S, Pentz R, Kodish ED. Informed consent for pediatric leukemia research: Clinician perspectives. Cancer. Aug 1; 2001 92(3):691–700. [PubMed: 11505417]
13. Denzin, NK.; Lincoln, YS. Handbook of Qualitative Research. 2nd ed.. Sage; Thousand Oaks, CA: 2000.
14. Denzin, NK.; Lincoln, YS. Collecting and Interpreting Qualitative Materials. Sage; Thousand Oaks, CA: 1998.
15. Estlin EJ, Cotterill S, Pratt CB, Pearson AD, Bernstein M. Phase I trials in pediatric oncology: Perceptions of pediatricians from the United Kingdom children's cancer study group and the pediatric oncology group. J Clin Oncol. May; 2000 18(9):1900–5. [PubMed: 10784630]
16. Helft PR, Hlubocky F, Wen M, Daugherty CK. Associations among awareness of prognosis, hopefulness, and coping in patients with advanced cancer participating in phase I clinical trials. Support Care Cancer. Oct; 2003 11(10):644–51. [PubMed: 12883963]
17. Daugherty CK, Ratain MJ, Siegler M. Pushing the envelope: Informed consent in phase I trials. Ann Oncol. Apr; 1995 6(4):321–3. [PubMed: 7619746]
18. Gilligan, C. In a different voice: Psychological theory and women's development. Harvard University Press; Cambridge, MA: 1993.
19. Sherwin, S. No longer patient: Feminist ethics and health care. Temple University Press; Philadelphia, PA: 1992.
20. Horng S, Grady C. Misunderstanding in clinical research: Distinguishing therapeutic misconception, therapeutic misestimation, and therapeutic optimism. IRB: Ethics & Human Research. 2003; 25(1):11–6. [PubMed: 12833900]

Table 1

Physician Characteristics (N = 103)

Physician Age	**Mean (SD)**	**42 years (9.5)**
Gender	Male	51 (49.5%)
	Female	52 (50.5%)
Race	White	83 (83%)
	Asian/Asian American	12 (12%)
	Hispanic/Latino	4 (4%)
	African American	1 (1%)
Physician Role*	Attending	83 (81%)
	Fellow	20 (19%)
Training	Only Informal Training	74 (79%)
	Formal and Informal Training	20 (21%)

* For our purposes, Attending is defined as a physician having completed residency and fellowship in pediatric oncology; while Fellow is defined as a physician currently in training for, but has yet to complete, a fellowship in pediatric oncology

Table 2

Physician self reported opinions about the ICP for pediatric Phase I trials based on the type of Informed Consent (IC) training they received

Outcomes	Informal Training N= 74	Formal Training N=20	P value p≤
Number 1 goal of ICP: To explain progression of the disease			
Yes	38%	15%	.050
Effect of ICP on parents' feeling of control			
More in control	52%	20%	
No effect on control	32%	30%	.004
Less in control	16%	50%	

ICP – Informed Consent Process

Table 3

Physician self reported opinions about the ICP for pediatric Phase I trials based on gender

Outcomes	Male N=51	Female N=52	P value
Effect of ICP on parents' anxiety			
Less anxious	38%	14%	
Have no effect on parents' anxiety	28%	26%	.008
More anxious	34%	61%	
Statement best describing approach to ICP			
I describe the Phase I study without any attempt to influence their decision	76%	52%	
I study and suggest that other children will benefit from what we learn in the study	20%	40%	.052
I explain the progression of the disease and its treatment options and recommend that the child go on the study	4%	8%	
Directiveness in recommending Phase I study			
Non-directive	59%	38%	.03
Number 1 goal of ICP:			
To provide information about study entry			
Yes	38%	60%	.029
Percent of parent who understand the meaning of toxicity *(Mean)* at the time of study enrollment	77.6	68.9	.045

ICP – Informed Consent Process

Table 4

Categorization of suggestions*

Category	Frequency (N = 63)	Percentage (%)
Simplify consent content, length and language	18	29
Formal Physician training	10	16
Improve communication with parents/patients	10	16
Staged informed consent process	9	14
Educational material for parents/patients	6	10
Emphasize goals of trial	4	6
Increase assistance from support HCPs‡	4	6
Other	2	3

*Suggestions from physicians to the question “How do you think we can make the Phase I informed consent process better”

‡Health care professionals