

**The Maternal and Child Health Research Program
Grant No. H1SMC06346
Promoting Pediatric Bioethics in Health Care and Research
Final Comprehensive Report, May 2007**

I. Introduction

The ethical basis of medical practice rests on the principle of beneficence, the obligation to do good to the patient. But delineating what is good or in the patient's best interest can be challenging. Practitioners work with patients from many backgrounds, cultures, and value systems. Inevitably, patient or family choices will be at odds with professional opinions regarding the proper course of an individual's medical care. When these differences in values between the medical professional and the patient are accompanied by alternative treatment choices, recent advances in technology, and complex tradeoffs, the task becomes even more difficult. If the patient is a child who must rely on parents to make decisions on his or her behalf, yet another dimension is added. Making good medical decisions requires more than scientific medical training. It requires that health care professionals recognize ethical issues, be able to identify the appropriate ethical framework for understanding and analyzing ethical issues, and be familiar with strategies for resolving conflicts of values that arise in the medical setting.

Ethical concerns are not limited to clinical medicine but also arise in medical research. These issues are particularly compelling when children are involved. As a group, children have much to gain from participating in research, yet there is often some risk involved for the individual participant. The goals of research differ from those of clinical practice. In the clinical context, the interest of the individual patient is the primary focus. The primary goal of research, on the other hand, is to produce generalizable knowledge that will hopefully benefit a future population of individuals. Research participants stand to benefit from any mechanism that serves to protect them from unnecessary harm, seeks to optimize direct benefits, and assures that the pediatric patient and family understand the procedures, risks, and benefits of participation. Some commentators have suggested that an advocacy program could promote communication and decision making in the research context, thus adding a layer of protection for research participants.

The purpose of this project was to enhance the ethical awareness and sensitivity of health professionals who care for children and researchers who enroll children as participants. The two primary goals of this grant included the development and implementation of a patient advocacy program for pediatric research and the development and implementation of a pediatric bioethics education program.

This project supported the implementation of pediatric bioethics education through a variety of mechanisms including web-based education modules, lectures and discussions of pediatric ethical issues within the WAMI (Washington, Alaska, Montana, and Idaho) region, and the creation of a Pediatric

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Bioethics fellowship training program and the implementation of a 'patient advocate' role in a pediatric research context.

II. Review of the Literature

Pediatric Bioethics in Health Care

Ethical difficulties are compounded in the medical setting by the inability of the child to make choices and provide legal consent. Because age, developmental limitations, and maturity limit the child's ability to make choices, surrogate decision-makers (usually the child's parents) are legally authorized to weigh the benefits and harms of proposed medical interventions and choose a treatment plan on behalf of the pediatric patient. Although trained bioethicists are increasing in number, few of these individuals focus their attention on issues specific to pediatric patients in the clinical and research environment. At the same time, most clinicians receive inadequate training for the ethical challenges they encounter in day-to-day clinical practice (Egan, 2002) and a lack of formal training in bioethics often leads to a poor understanding of essential ethical principles (Broome, 2001, Ondruek et al, 1998, Kodish, 2005).

Many tools have been proposed for dealing with ethical quandaries. Beauchamp and Childress (1994) offer the use of four ethical principles (respect for autonomy, beneficence, nonmaleficence, and justice) as a way of providing clarity to ethical disagreements. Principles help free our thinking from bias and can be applied to a variety of different situations. However, others have argued that while a principle-based approach can be useful, it can also be applied inappropriately. Individual character and the ability to understand relevant contextual features can be just as important as an understanding of principles (King and Churchill, 2000), making education surrounding the implementation of principles extremely valuable to clinical practice.

Pediatric Bioethics in Research

Well-designed research is necessary in order to improve the care of children who struggle with illness and disease. However, research within the context of clinical care can be confusing to families (Applebaum et al, 2004). Researchers may unintentionally encourage enrollment in a study because of their belief and enthusiasm for a project. The understandable enthusiasm an investigator may feel toward the study can create a potential conflict of interest if not managed (Morriem, 2001). When the researcher also plays the role of treating physician, distinguishing between the research protocol and standard care may be difficult for the pediatric patient and his or her family to understand (Diekema, 2003; Caldwell et al, 2004). The patient or family may not realize standard treatments are available outside of the research context, or whether research truly offers a prospect of direct benefit to the child. In addition, the respect many individuals hold for medical professionals can prove highly influential, especially when standard treatments have failed to cure or control a child's disease and a

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research protocol may seem like a family's only option for treatment. The literature demonstrates that research participants often do not understand the nature of a research project in which they are enrolled (Brown et al, 2004, Applebaum et al, 2004, Broome, 2001). For example, one government study of nearly 1900 adult research participants found that: "Patient-subjects frequently expressed the belief that an intervention [i.e. participation in research] would not even be offered if it did not carry some promise of benefit; many certainly assumed that the intervention would not be offered if it posed significant risk" (Advisory Committee on Human Radiation Experiments, 1995). While these results reflect the experiences of adult participants in research and little is known about how pediatric patients or their parents might struggle to understand the aims of research (Applebaum et al, 2004), it seems reasonable to conclude that the challenges would be similar.

To facilitate the ethical conduct of research involving children, increased attention to several facets of the research process is essential. These include optimizing communication between families and the research team, enhancing education of the family about the research process, ensuring that family members comprehend the information presented to them, and facilitating the voluntary participation of the family (Hurley & Underwood, 2002, Bruzzese and Fisher, 2003). The addition of an advocate role in the research context could potentially assist with these critical elements. A patient advocate acts as a liaison who can educate family members about the research culture and the overarching goal of research and assure that family members understand the distinction between the research protocol and standard treatment regimens. At the same time an advocate can partner with the research team to ensure that the interests of the family are supported if they choose to participate in the study. The overarching objective of an advocate role is to augment the existing research structure and encourage a collegial and collaborative research atmosphere.

III. Study Design and Methods

This project primarily used qualitative methodology including use of a focus group, interviews and observations to gain insight related to the development of the patient advocate role. The grant advisory committee was used to gather information regarding existing needs and the type of bioethics education materials that would be most helpful. Patients, families, and researchers who provided information through a focus group, interviews, and observations were identified from the Clinical Research Center, Hematology/Oncology and Rheumatology outpatient clinics, and other clinical services (Infectious Diseases, Craniofacial, Pulmonary, etc.). Children's Hospital and Regional Medical Center's Institutional Review Board (IRB) provided human subjects approval for the focus group and interviews. Interviews and the focus group used semi-structured formats and an observation tool (See Appendix A, Tools.) was

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developed to record field notes. QRS-N6 qualitative software was used to analyze interview data. Data from the observations were entered and analyzed using the Statistical Package for the Social Sciences 12.0.1.

IV. Detailed Findings

Pediatric Bioethics Education

The grant Advisory Committee provided input on the development of pediatric bioethics education modules, topics for lectures and discussions provided within the WAMI region, and the pediatric bioethics fellowship.

Pediatric Bioethics Case-based Education Modules

Education modules were developed by grant team members and the current pediatric ethics fellow, with input from bioethics program staff. Five teaching guides were developed and have been posted and can be downloaded from the Treuman Katz Center for Pediatric Bioethics website at <http://bioethics.seattlechildrens.org/education/education.asp> under the header Case Based Teaching Guides.

- **Informed Consent—Parental Refusal of Care**
- **Confidentiality and Adolescents**
- **Truthfulness in the Physician-Patient Relationship—Physician Fallibility, Medical Error and Disclosure**
- **Withholding Life-sustaining Treatment in the NICU**
- **Witnessing Incompetent or Inappropriate Behaviors**

Lecture/Discussions/Grant Rounds

The grant Advisory Committee was provided an opportunity to request pediatric bioethics education at sites within the WAMI region and Table 1 lists education provided.

Table 1. Lecture/Discussions provided in the WAMI region

Title	Parent Refusal of Immunizations	Adolescent Confidentiality	Growth Attenuation
Presented by	Doug Diekema, MD	Doug Diekema, MD	Jeff Botkin, MD Doug Diekema, MD Dan Gunther, MD
Date	September 2006	October 2006	March 2007
Place	Anchorage, Alaska	Pocatello, Idaho	Seattle, Washington
Format	Grand rounds	Lecture/discussion	Grand rounds
Participants	37	38	250

Pediatric Bioethics Fellowship

The Pediatric Bioethics Fellowship at the Treuman Katz Center for Pediatric Bioethics was developed in 2006 as a 2 to 3–year program that trains individuals

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in bioethics with an emphasis on issues that arise in pediatric patients in the clinical and research arenas. The Fellowship is offered by the Division of Bioethics within the Department of Pediatrics at the University of Washington School of Medicine and the Treuman Katz Center for Pediatric Bioethics at Children's Hospital and Regional Medical Center. Our first fellow, Douglas J. Opel, MD, started in July 2006. Fellowship activities are supervised by the fellowship director, Douglas Diekema, MD, MPH.

Core activities of the fellowship include participation in all Bioethics Center activities, participation in the clinical and research consultation services, membership on the Children's Hospital Ethics Committee and IRB, participation in Center educational seminars, bioethics teaching to fellows and residents, and enrollment in a degree program at the University of Washington that is expected to lead to a Masters in Public Health or similar degree. This degree program will include the core curriculum courses of biostatistics, epidemiology, and research design. Subsequently, the MPH coursework is chosen to meet the individual's educational needs, including courses offered through the Department of Medical History and Ethics.

Scholarly activity is required as part of the fellowship. The fellow will be expected to complete at least one original research project of his own design before the end of the two or three year fellowship. In addition, the fellow will be offered the opportunity to collaborate on other projects and papers as part of activities at the Center, collaborate with faculty on other academic activities including manuscript reviews, seminar planning, and administrative activities of the center, and participate in at least one scholarly presentation at a national professional meeting.

Patient Advocate Role Development

Early in role development, the position title of Patient Advocate was changed to Research and Family Liaison (RFL). This title change was made to more accurately describe the intended function of persons filling this role and to avoid the implication that others (like parents and research personnel) could not also act as advocates for a child. The term "Research and Family Liaison" better describes the role of facilitating communication between researchers and families.

Core Competencies

As the role was developed, a list of core competencies was created to guide training of newly hired RFLs. These competencies are listed in Table 2. Within the first two months of hire, training was provided by various individuals to increase skills related to these areas. At the end of the grant, self-perceived competency was assessed by the two RFLs using proficiency levels of novice,

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basic, advanced, or expert. The following depicts the results of the self assessment (each X represents the assessment of one of the two RFLs):

Table 2 Core Competency Assessment

Topic area	Novice	Basic	Advanced	Expert
Pediatric ethics			X	X
Childhood growth/development		XX		
Cultural Sensitivity			X	X
Communication			X	X
Family Centered Care		X	X	
Human Subjects Protection			XX	
Research Rules and Regulations			XX	
Role of Advocacy in Research		X	X	

The following topics were not included as core competencies but were viewed as very important for role success—knowledge of organizational change strategies, knowledge of quality management (methods to systematically improve practices) and health system knowledge, including organizational structure.

Interviews with researchers

Nine Children’s investigators were interviewed to identify challenges they encounter as they lead informed consent conferences, and to identify strategies researchers use or hope to use to improve the process of pediatric informed consent. The researchers also were asked how an RFL role could be developed to assist them or families with these challenges. Table 3 lists the primary and sub themes that emerged from analysis of these interviews.

Table 3. Primary and Sub Themes related to Investigator Challenges

Nature of the Study	<ul style="list-style-type: none"> • Complexity of the Study <ul style="list-style-type: none"> Therapeutic misconception Randomization Nature of risks • Children as Participants <ul style="list-style-type: none"> Assent Undue Influence and Coercion
Informed Consent Process	<ul style="list-style-type: none"> • Family Factors <ul style="list-style-type: none"> Severity of child’s illness Prior perceptions of research Culture and language <ul style="list-style-type: none"> - translation issues - skill of interpreter • Regulatory factors <ul style="list-style-type: none"> HIPPA

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	Consent forms <ul style="list-style-type: none"> • Consent conference • Time • Resources available to the family
Clinician/Researcher Role	<ul style="list-style-type: none"> • Benefit of dual role • Alleviating conflict of roles • Personal perceptions
Resources	<ul style="list-style-type: none"> • Help with consent forms • Training and tools • Staffing

Investigators offered the following suggestions regarding how RFLs might assist in improving the informed consent process for themselves and families:

- Create visual aids to clarify and highlight important information
- Help investigators contextualize risks
- Assist investigators in enhancing their presentation skills
- Provide education on the assent process
- Assist the institution in developing informed consent templates
- Explore issues related to non-English speaking family research participation

Family focus group

The purpose of the family focus group was to explore parents' experiences in research and provide meaningful input for the creation of the new Research and Family Liaison role. Seven families (9 parents) were recruited and agreed to participate in an audio-taped focus group facilitated by a social worker with more than 20 years experience in facilitating similar groups. The conversations were then transcribed and analyzed. These parents had a wide variety of experiences with research participation and all have a child with a cancer diagnosis. This focus group produced four major areas in which a families' experience in research could be improved: understanding, pressure, trust and resources.

Understanding

Focus group participants were in agreement that understanding the child's diagnosis was difficult due to medical complexities and their own emotional state. The presentation of research as an option increased the amount and complexity of the information provided and required them to make a decision for which they felt ill prepared.

Suggestions

- Provide written information about the diagnosis; including a list of websites
- Assist families in finding other individuals with whom they could speak (parents of children with the same or a similar diagnosis, researchers, etc)
- Create a list of questions families might want to consider regarding the different options presented (e.g. standard treatment, research studies)

Pressure

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Most parents felt a sense of urgency regarding decision making about their child's treatment options. Factors that contributed to this sense of urgency included their emotional state following the diagnosis, the language and behavior used by physicians, and the real time constraints dictated by the disease.

Suggestions

- Have doctors clarify the time frame required for a decision to be made and give specific reasons for the need to make decisions within that time frame.

Trust

The parent's sense of trust in physicians and the institution played a significant role in their ability to make a decision. This could be a problem since parents are required to make decisions shortly after a diagnosis without having established close relationships with the medical/research team. Even if trust was established early on, parents recognized that this could be detrimental if they became too trusting and began to delegate decision making exclusively to the research team.

Suggestions

- Include parents in team medical discussions regarding their child's care.
- Have researchers/doctors disclose their research interests
- Provide specific answers to parent's questions

Resources

Parents mentioned several types of resources that would have made their situation easier to navigate, and that in hindsight would have reduced some of the burden they experienced. These resources and tools also have the ability to help future parents experiencing a similar set of difficult circumstances and range from simple comments the staff could incorporate to major institutional changes.

Suggestions

- Offer a list of available resources for parents at the hospital (e.g. support person(s) or groups, contact numbers, information and educational resources such as hospital library, books, videos and websites)
- Assign an individual to each family who could act as their main contact
- Provide a list of questions parents might want to ask about research

Observations and field notes

The two RFLs observed consent conferences to familiarize themselves with the current manner in which these conferences are conducted, and in order to identify potential opportunities for RFLs to improve and enhance the consent process. An Observation Tool was developed to assist RFLs in systematically collecting information during observed consent conferences that was later analyzed to provide a one-time snapshot of the informed consent process. The tool allows the observer to rate the degree to which ethically required information (13 items) was explained to parents and to evaluate communication skills and the context (7 items) of the consent conference. Five questions assessed select aspects of cultural sensitivity when communicating with families with limited English proficiency.

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The convenience sample consisted of research staff from two clinical areas who volunteered to have RFLs observe consent conferences. A total of 33 non-duplicative observations were recorded by two RFLs during the project period. Hematology-oncology studies represented nearly 70% (23/33) of the consent conference observations and rheumatology 30% (10/33). Nine different investigators were observed during these conferences, although three investigators accounted for nearly two-thirds of the total observations. English was the primary language for over 90% of families and interpreters were required in only 2 of 33 consent conferences. Findings from these consent conference observations include the following:

- Research study and population. The two clinical areas provided vastly different experiences for observation of consent processes. Research and treatment are intricately entwined when the patient has cancer. During the time of a cancer diagnosis, most parents/patients are offered a choice of standard treatment or participation in research. Stress related to the diagnosis, the introduction of new terminology and additional information about potential research participation contribute to the complexity as parents must make decisions regarding their child's care. In contrast, studies in rheumatology often involve a one-time visit and agreement to provide a blood sample or answer a survey. These diverse settings provided an opportunity to observe how the role might differ in various types of research. In research involving complex clinical studies, ongoing involvement of RFLs throughout the consent process would be warranted. RFLs as advocates at consent conferences for single-visit, non-complex research appeared to have little value added. During these conferences, however, RFLs could serve as educators regarding staff communication and presentation skills.
- Context. Contextual issues such as setting (room size, number of people, extraneous noise, multiple children with parents, etc.), communication style (eye contact, pace of speech, use of lay language, etc.), and communication skills (listening, assessing understanding, tailoring information, etc) can greatly affect parent and patient perception and understanding.
- Informed consent is a process not an end result. The consent process involves not only providing information, but assessing understanding, clarifying misconceptions, facilitating decision-making, and continuous conversations to affirm rights and responsibilities. Facilitating an informed decision regarding research participation is the primary objective, not obtaining a signature on a consent form, and RFLs could enhance many of these facets within the consent process.
- Complexity of implementing a new role. Although both clinical areas agreed to participate in this role development phase, it was difficult to insert a new role into an established process and communication was not always clear--for example, staff felt the role was created to monitor their performance rather than facilitate communication. It took a great deal of time and effort to develop systems that allowed RFLs to view consent conferences. Providing

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information to the research teams about RFL findings was important throughout role development. Despite these difficulties, the value of the RFLs has been recognized over time.

- Family response. All families were asked if an RFL could observe their consent process and more than 90% agreed. Family response seemed to be positive, although further study is needed.

IV. Discussion and Interpretation of Findings

Pediatric Bioethics Education

The Pediatric Bioethics Fellowship was successfully created and implemented during the grant period. The current fellow is completing his first year, has enrolled in the MPH program in Health Services with a focus on bioethics, and has already successfully published one manuscript, has prepared an additional manuscript for submission, and has begun work on his major research project on using a quality improvement framework in the context of ethics consultation. He has been actively engaged in Center activities, authored one of the bioethics education modules, and has led several teaching sessions in the hospital.

Research and Family Liaison Role Development

Literature supports the development of a patient advocate role in the research setting. There is little guidance available in the literature on how to develop this role or the responsibilities that should be included as part of such a position. This grant provided opportunities to learn from others—principal investigators, research team members, families, clinicians and administrative personnel—about existing needs and opportunities for developing such a role.

Over the past 1 ½ years the RFL role developed primarily in two areas—advocacy and education. In many situations, these two facets occur simultaneously as RFLs worked with families and researchers to assist in facilitating communication and decision making. While working with families RFLs developed trusting relationships, assisted families in developing and asking questions to clarify information provided by research staff, and reassured families about their rights in research participation. In working with researchers, RFLs provided insight about family needs for clarification or more information, developed visuals that helped the researcher explain complex studies, and assisted the researcher in implementing research guidelines and policies.

Data gathered from the focus group, researcher interviews, and observations both informed role development and identified general needs and challenges that exist within the research environment. This led to the development of an educational program, the Consent, Assent and Parental Permission (CAPP) Mentoring Program. The purpose of this program is to improve communication skills of researchers and research staff when engaging families in decisions about participation in clinical research. It includes a series of background

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lectures and discussions on regulatory, ethical and communication issues related to the informed consent process. As part of the program, participants observe consent discussions led by peers. Participants then apply what they have learned to interactions with families while program instructors (the RFLs) observe these interactions and provide feedback to participants about the effectiveness of their communication with families. An RFL who is bicultural and bilingual in Spanish leads one session on policies and practical aspects of research participation by families with limited English proficiency. CAPP will be offered four times a year and is open to all research staff who interact with families. After the grant ended, a focus group of families who are monolingual in Spanish was held to determine their research participation needs. Learning from parents who speak other languages will provide much needed information about barriers that prevent families with limited English proficiency from participating in research and ways in which their participation can be made more meaningful.

The RFLs are collaborating with Children's Human Subjects Protection Program (HSPP) to develop templates for consent forms that use parent-friendly language to describe common tests, procedures, and research terms.

Children's Hospital Research Institute is committed to continuous support of the Research and Family Liaison role. As the role continues to develop, further research will be undertaken to continuously improve consenting processes, research staff competency and confidence in communicating with families, and to understand effects of having Research and Family Liaisons involved with families as they learn about participation in complex research studies.

VI. List of Products.

1. American Society for Bioethics and Humanities Annual Conference, Washington, DC. October 2007. Abstracts submitted:
 - a. Salas, H., Simon, C; Solomon, M. Creating Connections: Enhancing Relationship-based Approaches to Informed Consent in Clinical Research
 - b. Opel, D. Ethical Dilemmas as Sentinel Events: A Case Study in Applying a Quality Improvement Technique to Ethics Consults
2. Salas, H; Aziz, Z; Villareale, NL; and Diekema, D, Enhancing the Consent Process: The Research and Family Liaison Role (working title) will be submitted to [IRB: Ethics & Human Research](#) in summer 2007.
3. Consent, Assent and Parental Permission Mentoring Program Syllabus <http://bioethics.seattlechildrens.org/education>
4. Bioethics Case-Based Education Modules can be found at <http://bioethics.seattlechildrens.org/education/education.asp>
5. Opel, DJ. The Ethics of Quality Improvement: Provider Obligation and the Role for External Oversight Ambulatory Pediatric Association/Pediatric Academic Societies Annual Conference, Toronto, Ontario, Canada, May 2007

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Appendix A

Tools

Researcher Interview Questions
Family Focus Group Questions
Consent Conference Observation Tool

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Researcher Interview Questions

1. What are the areas that regularly seem to confuse families who take part in research? What methods do you employ to clarify these areas?
2. What difficulties have you encountered with families and their participation in the research process?
3. Have you experienced any cross-cultural communication difficulties with families involved in the research process? Please explain.
4. Have you experienced difficulties related to your being both the researcher and the care provider for a child? Please explain.
5. How do you assist children in understanding research participation?
6. Do you believe current methods of obtaining meaningful consent are effective? What suggestions do you have to improve the process?
7. In responding to IRB regulations and requirements, are there any areas where it would be helpful to have someone to assist in developing information for research participants (for example help with constructing consent or assent forms)?
8. What resources would assist you in working with families who will be approached to participate in research or who are currently participating in research?

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Family Focus Group Questions

1. What words first come to mind when you hear the word RESEARCH?
2. Who presented the study to you? If the treating physician presented the study, did that make you more apprehensive or comfortable?
3. What were the circumstances in which the study was presented?
4. What other options were presented to you?
5. In retrospect, is there anything you wish you would have known before deciding to participate in research?
6. What should guide the research agenda at Children's?
7. In your opinion, what is the difference between clinical care and research?
8. How well was the study information presented?
9. How was your child included in the discussion and decision-making process?
10. Did you feel that your participation was voluntary (i.e. that you had a choice between different options)?
11. Why did you decide to participate?
12. What was communication between your family and the research team like?

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**Observation of CONSENT Conferences Specific to Research
PROMOTING PEDIATRIC BIOETHICS IN HEALTH CARE AND RESEARCH**

Date:

RFL code:

Research study code:

Presenter code:

Child Present: Yes No

Child's Age:

Interpreter present: Yes No

If yes, record the family's native language:

Conference length:

The purpose of this tool is to collect baseline data related to the informed consent process in Pediatric Research to inform the Research and Family Liaison role.

Directions: Please indicate the degree to which you agree with each of the following statements by placing an **X** in the box that best matches your observation.

Please explain your response in the comment section, **especially when you check somewhat agree, somewhat disagree or strongly disagree.**

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The presenter explained:	Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree	NA	Comments
The voluntary nature of the family's participation						
The purpose of the research study e.g. including difference between research and treatment						
The research procedures						
The presenter explained:	Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree	NA	Comments
The risks and potential discomfort associated with the research						
The potential benefit to the child of research participation						
The family's responsibilities e.g., time, activities						
The family's ability to refuse or stop at anytime w/o penalty or loss of benefits						
Alternative treatments or procedures						
The steps taken to protect confidentiality						

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How and if families will receive research results						
Whom to contact with questions regarding the research, participant rights, and in case of injury						
Any payment or incentive available to families who participate in the research						
Any costs/expenses the family will be responsible for						

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Overall, the presenter:	Strongly Agree	Somewh at Agree	Somewh at Disagree	Strongly Disagree	NA	Comments
Helped the parent(s) feel at ease e.g. breaking the ice, listening, demeanor, eye contact, pacing etc.						
Communicated in a manner that the parent(s) could understand e.g. avoided medical jargon, explained special terms, etc.						
Provided information tailored to the family's information preferences/needs e.g. less or more detail						
Encouraged and allowed time for the parent(s) to ask questions						
Included the child when communicating with the parent(s) about consent						
Assessed the parent(s) understanding through the use of open-ended questions, or other methods						
Encouraged the family to take the time they needed to make a decision						

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If the family (or some of the family) is Non-English Speaking and an interpreter is used please complete the following:

Did the family receive consent/assent forms in their native language prior to the meeting?

Yes No Explain:

The presenter:	Strongly Agree	Somewh at Agree	Somewh at Disagree	Strongly Disagree	NA	Comments
Met with the interpreter prior to the conference to establish how best to work with each other						
Ensured that the family received consent and assent materials in their native language						
Ensured that the interpreter received consent materials in the family's native language						
Was aware of and followed IRB protocol for signing of consent and assent forms with non-English speakers						