Children Enrolled in Parents’ Research:  
* A Uniquely Vulnerable Group in Need of Oversight and Protection  

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| Table 1. Recommendations for Procedural Safeguards When IRBs Permit Investigators to Enroll Their Children in Their Own Studies |
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| **Issue** | **Ethical Concern** | **Procedural Safeguard** |
| Parent-child relationship | The relationship may suffer harm as it shifts between parent-child and investigator-research participant. For example, there are added risks of breaches of confidentiality and privacy regarding disclosure of child’s information to parent. | The parent-investigator might be required to engage in an evaluation of the risk of harm to the parent-child relationship; this might be undertaken with an independent consent monitor or via a permission request form submitted to the IRB (see Table 2 for suggested topics for inquiry). |
| Parental permission | As a member of the research team, parent may be unable to provide unbiased assessment of risks/benefits to child. | a) All incentives relating to enrolling participants should be disclosed to the IRB; when the incentives are financial, limits might be imposed.  

b) For protocols requiring one-parent permission, permission should be obtained from the parent who is not the parent-investigator; for protocols requiring two-parent permission, independent consent monitoring might be required by the IRB. |
| Child assent | Child might feel special pressure to assent or have unexplored mixed motivations that diminish the voluntariness of his or her assent. Voluntariness to withdraw is also a concern. | Independent consent monitoring, including age-appropriate interviewing of child-participant about his or her motivations and expectations related to the research participation, might be required by the IRB (see Table 3 for suggested topics for inquiry). |
| Scientific objectivity | Investigator-parent may be unable to objectively assess his or her child’s data, including the occurrence of adverse events. Tainted data threatens scientific validity of study, a requirement of ethical research. If the child receives more attention than other research participants, questions of fairness also arise. | Another member of the research team should interact with the child, review data related to the child, and monitor the child’s safety. |
Table 2.
Questions for Parent-Investigators to Consider Either Independently or as Prompted by an IRB or Independent Consent Monitor

1. Why do I want my child to participate in my study?
2. How will participation affect my relationship with my child in the present or future?
3. Is this a joint decision that both parents support?
4. Might my child feel pressure from me to participate?
5. How will I avoid my child’s feeling that s/he has let me down if s/he decides not to participate or to withdraw before the study is over?
6. Can I objectively study my own child, or can research procedures be modified to prevent bias (such as having another team member interact with or review data relating to my child)?
7. What procedural safeguards will I implement to protect against breaches of confidentiality of my child’s data to me?

Table 3.
Examples of Questions for Independent Consent Monitors/Research Subject Advocates to Cover When Discussing Research Participation with Child

1. Why do you want to be in this study?
2. Do you feel that you can say no if you do not want to be in the study?
3. Do you feel like you could say “stop” if you later decide you do not want to be in the study anymore?
4. You should know that your parent might ultimately hear or see the information gathered from you in this study and know what you discuss in the context of the study even if there are safeguards against this. Is this acceptable to you?
5. Would you feel comfortable with me checking in with you again? (for longer term studies)