

Table 1: Characteristics of Survey Respondents (N = 41)

<i>Characteristic</i>	<i>Number</i>	<i>Percent</i>
Affiliated with the medical center (other than membership on IRB)		
Yes*	24	59%
No†	17	41%
IRB chair		
Yes	6	15%
No	35	85%
Professional experience in child health or development		
Yes	21	51%
No	20	49%
Duration of IRB membership		
<1 year	3	7%
1–4 years	19	46%
5 years	19	46%
Current or prior involvement as an investigator or research study staff		
Principal investigator	6	15%
Coinvestigator or other study staff	9	22%
None	26	63%
Number of new protocols undergoing full-committee review each year		
25–49	13	32%
50–99	20	49%
100–299	5	12%
Not sure	3	7%
Number of IRB meetings attended each year		
6–11	30	73%
12 or more	11	27%
Percent of protocols reviewed by the IRB that enroll primarily children		
≤10%	4	10%
11–24%	8	20%
25–49%	13	32%
50% or more	13	32%
Not sure	3	7%
Initial training received‡		
Computer-based tutorial	23	56%
Paper-based tutorial	9	22%
Video tutorial	7	17%
Lecture, workshop, or in-person tutorial	21	51%
Other	6	15%
No training	8	20%
Receipt of ongoing training		
Yes	31	78%
No	9	23%
Prior training in review of pediatric protocols		
Yes	28	68%
No	13	32%

*Includes six physicians, four nurses, one social worker, five pharmacists, one statistician, two administrators, one chaplain, one lawyer, one therapist, one risk manager, one vendor, and one volunteer.

†Includes six physicians, one lawyer, five community members, one ethicist, two retired physicians, and one retired nurse.

‡ Respondents could identify more than one type of training.

Table 2: Correlates of Self-Reported Preparedness for Overall and Pediatric-Specific Protocol Review

<i>Item*</i>	<i>Preparedness for Protocol Review</i>		<i>Pediatric-Specific</i>	
	<i>Overall</i>	<i>p-value</i>	<i>Median (Interquartile Range)</i>	<i>p-value</i>
IRB chair				
Yes	89 (83–100)	0.05	84 (71–100)	0.35
No	77 (63–85)		75 (64–93)	
Receives ongoing IRB training				
Yes	83 (75–92)	0.01	79 (71–96)	0.02
No	61 (54–73)		64 (50–75)	
Receives training in pediatric research review				
Yes	83 (77–100)	0.02	86 (75–100)	0.03
No	75 (61–84)		73 (63–88)	
Number of IRB meetings attended per year				
6–11	75 (61–83)	0.02	73 (64–89)	0.06
12 or more	85 (83–98)		86 (79–96)	

* Status as affiliated/unaffiliated member, prior professional experience in child health or development, prior experience as a principal investigator or other study staff, years of IRB experience, number of protocols reviewed per year, percent of protocols reviewed that are primarily pediatric, and type of initial training received were unassociated with self-reported preparedness for overall and pediatric-specific protocol review.

Table 3: Knowledge of Federal Regulations Regarding Review of Pediatric Clinical Research

<i>Question</i>	<i>Best Answer*</i>	<i>Number (Percent) Selecting Best Answer</i>
Which statement regarding parental permission for a child's involvement in IRB-approved research is correct?	Permission of both parents, if they are reasonably available, is required for research that lacks the prospect for direct benefit and involves a minor increment over minimal risk.	3 (8%)
According to the regulations, children are considered capable of assent when:	The IRB determines that they are capable of assent on the basis of age, maturity, and psychological state.	11 (27%)
Federal regulations define the concept of "minimal risk" as situations where:	The anticipated risks of participating in the research are not greater than those ordinarily encountered in daily life.	16 (40%)
Which statement about child assent is correct?	An IRB may waive the requirement for assent if the research offers benefits to the child that are unavailable outside the research.	11 (28%)
Which statement regarding the ability of an IRB to approve pediatric research is correct?	An IRB can approve a protocol that presents a minor increase over minimal risk if it determines that the research is likely to yield generalizable information about the subject's disorder or condition.	12 (30%)

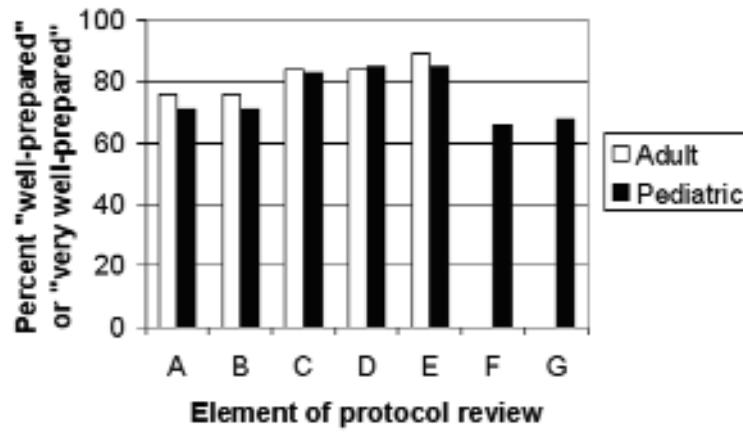
*A table that includes all response options is provided in the appendix (online at <http://www.thehastingscenter.org/Publications/IRB/Default.aspx>).

Table 4: Correlates of Knowledge Score

<i>Item</i>	<i>Knowledge Score Median (Interquartile Range)*</i>	<i>p-value</i>
IRB chair		
Yes	2.25 (1–3)	0.04
No	1 (0–2)	
Received lecture- or seminar-based training to prepare for IRB position		
Yes	1 (1–2.75)	0.02
No	1 (0–2)	
Received training specific to pediatric review process		
Yes	2 (1–2.5)	0.04
No	1 (0–2)	

* Knowledge score was unrelated to status as an affiliated vs. unaffiliated IRB member, prior professional experience in child health, or development; prior participation in a protocol as a principal investigator, coinvestigator, or study staff; years of IRB service; number of protocols reviewed by the respondent's IRB; percent of protocols reviewed by the respondent's IRB that are primarily pediatric; or receipt of ongoing education regarding IRB review.

Figure 1. Respondent Preparedness for Adult vs. Pediatric Protocol Review



Appendix – Complete Knowledge Questionnaire

<i>Question</i>	<i>Response Options</i>	<i>Number (%) Selecting Answer</i>
Which statement regarding parental permission for a child's involvement in IRB-approved research is correct?	Best	Permission of both parents, if they are reasonably available, is required for research that lacks the prospect for direct benefit and involves a minor increment over minimal risk. 3 (8%)
	Alternatives	Parental permission is always required before a child can participate in clinical research. 28 (74%)
		Parental permission may be waived whenever the research poses no greater than minimal risk to the child. 0 (0%)
		Permission of both parents, if they are reasonably available, is required for research that offers the prospect of direct benefit to the child but carries substantial risks. 6 (16%)
	Not sure 1 (2%)	
According to the regulations, children are considered capable of assent when:	Best	The IRB determines that they are capable of assent on the basis of age, maturity and psychological state. 11 (27%)
	Alternatives	They are at least seven years of age and of normal cognitive ability. 9 (22%)
		They are at least twelve years of age and of normal cognitive ability. 10 (24%)
		Their parents determine that they are capable of assent on the basis of age, maturity and psychological state. 6 (15%)
	Not sure 5 (12%)	
Federal regulations define the concept of "minimal risk" as situations where:	Best	The anticipated risks of participating in the research are not greater than those ordinarily encountered in daily life. 16 (40%)
	Alternatives	The anticipated risks of participating in the research are not greater than those ordinarily encountered during the course of the subjects' medical care. 9 (22%)
		The anticipated risks of participating in the research are only slightly greater than those ordinarily encountered in daily life. 4 (10%)
		The anticipated risks of participating in the research are only slightly greater than those ordinarily encountered during the course of the subjects' medical care. 11 (28%)
	Not sure 0 (0%)	

Appendix – Complete Knowledge Questionnaire (cont'd)

<i>Question</i>	<i>Response Options</i>	<i>Number (%) Selecting Answer</i>
Which statement about child assent is correct?	Best	An IRB may waive the requirement for assent if the research offers benefits to the child that are unavailable outside the research. 11 (28%)
	Alternatives	An investigator can assume that a child has assented to research participation as long as the child does not voice an objection. 1 (2%)
		An investigator can assume that a child has assented to research participation as long as the child does not voice an objection, provided that the parent agrees with this assessment. 8 (20%)
		Assent can be waived if the parent thinks that the purpose of the research is sufficiently important. 6 (15%)
Which statement regarding the ability of an IRB to approve pediatric research is correct?	Best	Not sure 14 (35%)
		An IRB can approve a protocol that presents a minor increase over minimal risk if it determines that the research is likely to yield generalizable information about the subject's disorder or condition. 12 (30%)
	Alternatives	To approve a protocol that presents greater than minimal risk, the IRB must determine that the research offers the prospect of direct benefit to the child. 13 (33%)
		An IRB must refer all protocols enrolling children that present greater than minimal risk and no prospect of direct benefit to the child to the Department of Health and Human Services. 2 (5%)
		An IRB can approve a protocol that presents a minor increase over minimal risk only if it also offers the prospect of direct benefit to the child. 8 (20%)
		Not sure 5 (12%)
