Obtaining Department of Pediatrics Approval of IRB Proposals

IRB applications submitted by Principal Investigators from the Department of Pediatrics require scientific review recommendation of approval and, approval by the office of the Chair of the Department of Pediatrics. Departmental approval of IRB applications is coordinated by the Pediatric Clinical Research Office (PCRO).

	IRB Approval Checklist *(New IRB Applications and 5-Year Renewals)*
	Investigative Team develops research proposal and obtains scientific review
	Investigative Team prepares IRB Application in E-IRB
	PI submits (signs-off) IRB application in E-IRB system
	PI / Coordinator prepares ***Pediatrics Clinical Proposal Sign-Off Form*** \\Nt005\peds_shr\Public File Exchange Folder\ClinicalResearch Office\FORMS\PCROSignoff_Form.doc *For guidance contact the PCRO X31727; Room 4-7219*
	ATTACH THE FOLLOWING PRINT DOCUMENTS TO THE PEDIATRIC SIGN-OFF FORM
	• Evidence of scientific review and approval (see acceptable evidences below) • Protocol synopsis or abstract
	Deliver completed pediatric sign-off form and attachments to Pediatric Administration Rm 4-7218
	THE FOLLOWING ADDITIONAL PRINT DOCUMENTS ARE REQUIRED AS APPLICABLE:
	The project is Departmental Research:
	• The full protocol • Subject Consent / Assent documents
	A federally sponsored project approved previously by the Department of Pediatrics ***e.g. NIH Just-In-Time or Other Federal Agency***
	• Notification of approval for funding pending receipt of IRB approval documentation
	Industry Sponsored Clinical Research – Investigator Initiated Study
	• Protocol activities schedule • Subject Consent / Assent documents
	Federally funded collaborative group study e.g. COG, ACTG
	• Notice of study approval by collaborative review group • Subject Consent / Assent documents
	All other sponsored research e.g. Foundations
	• Protocol Activities Schedule • Subject Consent / Assent documents
	Requests for IRB study exemption
	• The full protocol
	Industry Sponsored Clinical Trial – Submission to WIRB
	• Print copy of the entire application, protocol, consent forms, and other documentation

	Acceptable Evidence of Scientific Review
	Dated, letter of approval from a University review group e.g. Cancer Center CTO, Perinatal Committee
	Dated, letter of approval from Pediatric Division review group or PCRO Scientific Review Committee
	Notification from federal sponsor requesting submission of IRB approval of the study *e.g. NIH Just-In-Time*
	Notification of study approval by collaborative study group e.g. POG, ACTG
	PCRO Administrative Review Approval (IRB Exemption Requests and Chart Review Studies)
	Note: MPH Thesis Projects require Committee Chair approval before submitting IRB application
	Notice of funding by health organizations and foundations accepted on case-by-case basis only

SIGNATURES MATRIX FOR IRB APPROVALS

Approval signatures documented on the Department of Pediatrics Clinical Research Proposal Sign-Off Form (PCRO form) and/or the University of Rochester Institutional Sign-Off Form (ORPA form).

IRB Application Protocol Type	Chief Sign	Chair Sign	PCRO Sign
"Just In Time" IRB proposals for peer reviewed Sponsored Project approved previously by the Chair i.e. federal agencies, national health organizations			X
Departmental Research Project	X	X	X
Federally funded Collaborative Group Multiple Protocols (COG, ACTG) Each new protocol	X	X	X
Funded peer reviewed sponsored project approved previously by the Chair Single protocol study			X
Request for IRB study exemption (minimal risk studies)	X		X
5-Year IRB Renewal of funded study approved previously by the Chair	X		X
5-Year IRB Renewal of Departmental Research Project	X	X	X