

NHRPAC* Risk Level	Examples from NHRPAC	Regulatory Categories to Consider
Minimal Risk	Venipuncture/fingerstick/heelstick Single Chest x-ray Bone density test Vision testing/Hearing testing Complete neurological exam Oral glucose tolerance test Standard Psychological tests Single subcutaneous or intramuscular injection (depending on the substance injected) Nasogastric tube insertion Indwelling heparin lock catheter (under certain conditions) MRI (no sedation)	45 CFR 46.404 / 21 CFR 50.51
Greater than minimal risk with prospect of direct benefit to individual	Some organ biopsies Phase 1 Pharmacokinetics Studies (under certain conditions) Imaging Studies Most IND and IDE studies	45 CFR 46.405 / 21 CFR 50.52
Minor increase over minimal risk without prospect of direct benefit to individual, but likely to yield generalizable knowledge about child’s disorder or condition	Urine via catheter Lumbar puncture Skin punch biopsy w/topical pain relief Bone marrow aspirate w/topical pain relief Small amount of additional tissue obtained at surgery MRI (with sedation, depending on the amount and duration of sedation)	45 CFR 46.406 / 21 CFR 50.53

*Report from the National Human Research Protections Advisory Committee(NHRPAC): Clarifying Specific Portion of 45 CFR 46 Subpart D that Governs Children’s Research

Stanford University HRPP Guidance	45 CFR 46 Subpart D –Risk Level in Pediatric Research	GUI-01042 2/2
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Resources	
NHRPAC	<ul style="list-style-type: none"> • Report from the National Human Research Protections Advisory Committee(NHRPAC): Clarifying Specific Portion of 45 CFR 46 Subpart D that Governs Children’s Research
OHRP	<ul style="list-style-type: none"> • OHRP Policy & Guidance – Vulnerable Populations: Special Protections for Children as Research Subjects