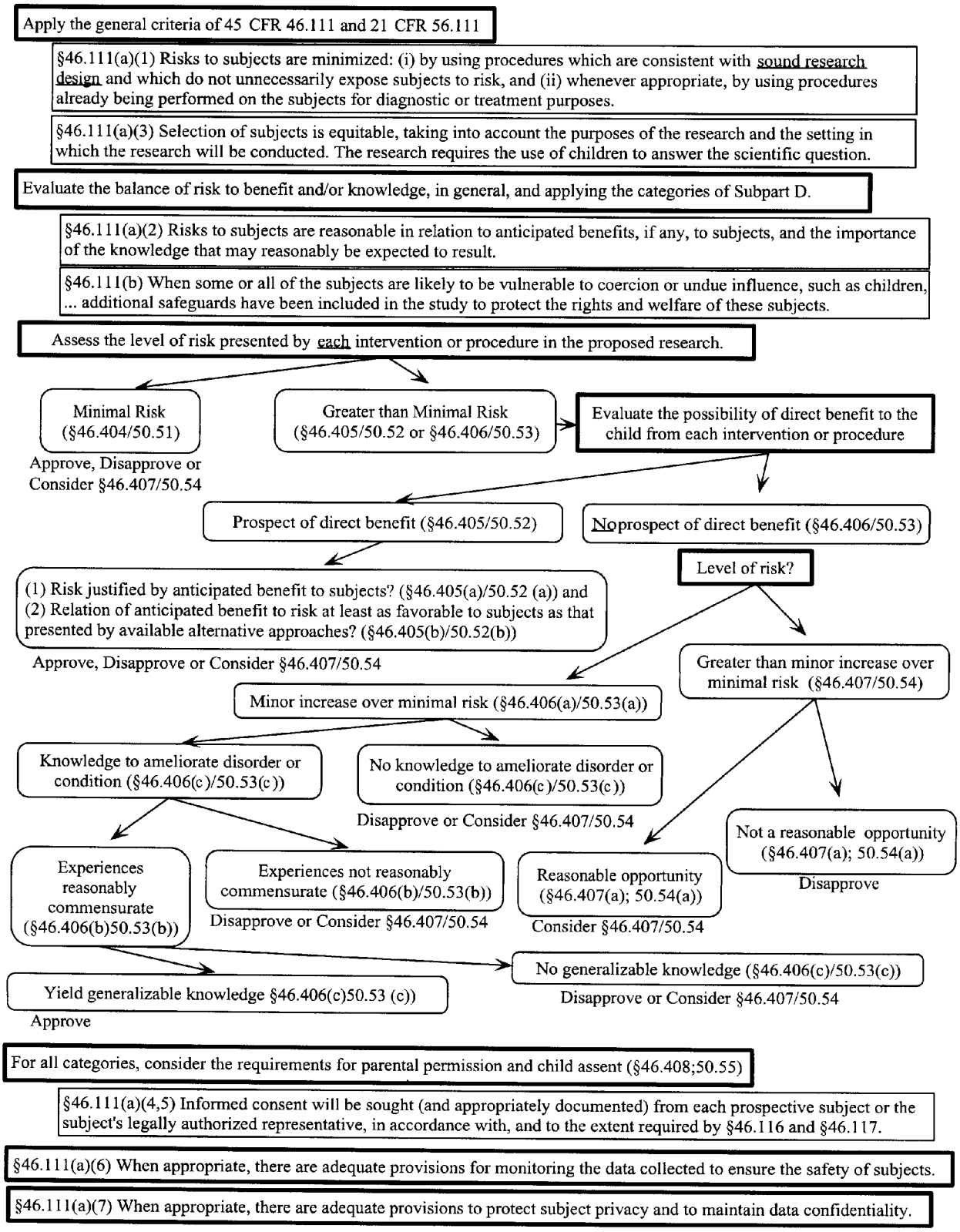ALGORITHM FOR SUBPART D ANALYSIS (45 CFR 46 AND 21 CFR 50)