ALGORITHM FOR PEDIATRIC PROTOCOL ANALYSIS (SUBPARTS A AND D - 45 CFR 46 AND 21 CFR 50)

Section One - Subpart A; and Section Three - Parental Permission and Child Assent

Section One - Subpart A

Evaluate the research proposal and apply the general criteria of Subpart A [45 CFR 46.111; 21 CFR 56.111]

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Ensure that risks to subjects are minimized by using procedures which (i) are consistent with sound research design; (ii) don't expose subjects to unnecessary risk; (ii) are already being performed for diagnostic or treatment purposes. [§46.111(a)(1); §56.111(a)(1)]

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Ensure that selection of subjects is equitable, taking into account the research purpose(s) and the setting in which the research will be conducted. The research should require the use of children to answer the scientific question(s). [§46.111(a)(3); §56.111(a)(3)]

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Evaluate the anticipated benefits, if any, of the research to subjects, and the importance of the knowledge that may reasonably be expected to result.[§46.111(a)(2); §56.111(a)(2)]

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Ensure that additional safeguards have been included to protect the rights and welfare of children. [§46.111(b); §56.111(b)]

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Apply the additional safeguards of Subpart D. See Section Two - Subpart D. →

Section Three - Parental Permission, Child Assent and Additional Subpart A

→ §46.111(a)(4,5) Informed consent sought (and documented), to extent required by §46.116 and §46.117.

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For all Subpart D categories, consider the requirements for parental permission and child assent (§46.408;50.55)

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Waive assent if (a) capability of some or all children so limited that they cannot reasonably be consulted or (b) research intervention or procedure offers prospect of direct benefit that is (i) important to children's health/well-being and (ii) available only in research.

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Permission of one parent sufficient (§46.404/405; §50.51/52); permission of both parents necessary unless one parent deceased, unknown, incompetent, or not reasonably available, or only one parent has legal custody of the child (§46.406/46.407; §50.53/54).

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§46.111(a)(6) When appropriate, there are adequate provisions for monitoring the data collected to ensure the safety of subjects.

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§46.111(a)(7) When appropriate, there are adequate provisions to protect subject privacy and to maintain data confidentiality.

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