

Let's be
“Reasonable”
about this....

Guidance: Consent and Not Reasonably
Available

Risk Level 46.406/50.53

- Research involving greater than minimal risk to subject with no prospect of direct benefit to individual subjects, but likely to yeild generalizable knowledge about the subjects' disorder or condition.
- Requires permission of both parents, "if reasonably available"

Examples of Appropriate 46.406/50.53 Determinations

- Drug studies with placebo
 - Using Component Analysis- active arm participants could be given a 46.405/50.52 risk determination as there is prospect of benefit from receiving the drug.
 - But placebo arm participants could be deemed no direct benefit and require a 46.406/50.53 **the FDA revised guidance stating that just “extra monitoring” should not be considered a benefit, however there may be other interventions in the placebo arm that do provide benefit**
- Research involving experimental donation of stem cells- sibling is subject. No “direct benefit”, and as a healthy sibling, procedure is greater than minimal risk.

Process of obtaining permission of both parents

- Can be independently of one another, at different times and different methods (in person, phone, fax, email, etc)
- If in shared custody, both parents wishes must be honored. Need to have 2 "yes's"
- Reasonably Available applies to both whereabouts AND the mechanism to get that consent

How “reasonably unavailable” are we talking?

YES (common)

- Parent is incarcerated (even this could be a no....)
- Parent on military duty (could also be a no...)
- Whereabouts unknown
- Parent lives off the grid- only had flip phone and no computer/fax*
- Parent is contacted but refuses to participate in the process (doesn't refuse the research)
- Multiple attempts are made to contact parent with no success and research may be time sensitive
documentation is key

Sorry...but no

- Dad is a jerk
- Mom is traveling overseas and can't talk until later tonight.
- Parents both have custody but hate each other and one doesn't want to call the other
- Coordinator has dinner plans and doesn't want to spend that much time on it

So....

