

# BPCA Priority List of Needs in Pediatric Therapeutics Sample Nomination

Please identify and list the proposed drug, biologic, or medical device to be investigated, along with the proposed pediatric indication of concern.	Drug/Biologic/Medical Device: lithium (drug)
Please list the proposed Therapeutic Area in which the proposed drug, biologic or medical device is to be investigated and the potential impact of a study in this area.	Psychiatry
Please submit a single sentence that frames your research question about the use of the drug, biologic, or medical device. Be sure to include the specific indication and outcome measure to be investigated.	More information is needed on the pharmacokinetic (dosing), short-term effectiveness, and tolerance in pediatric patients ages 10-17 years. Information is also needed on the long-term efficacy and safety for lithium in bi-polar pediatric patients.
For the proposed nomination, what study design would be most effective in providing the needed evidence in pediatrics?	Select all that apply: <ul style="list-style-type: none"> <li><input type="checkbox"/> Synthesis of existing evidence (e.g., systematic review, meta-analysis)</li> <li><input type="checkbox"/> Primary research using prospective data collection without randomization (e.g., observational study)</li> <li><input checked="" type="checkbox"/> Primary research through a prospective randomized trial</li> <li><input type="checkbox"/> Other (please describe)</li> </ul>
Understanding that there is the potential for ethical concerns with research involving pediatric populations, please describe any potential ethical considerations relevant to the nominated research study.	Conducting a placebo controlled study in mental health is very challenging. However, if we provide close assessments and rescue medications, then the design is possible.
Please describe any existing evidence available regarding the proposed research question and the feasibility of the proposed research question, as it relates to the following considerations:	There is limited existing data on the long-term effectiveness and safety of this drug in the pediatric population. Many patients are on antipsychotics which can lead to a myriad of metabolic derangements. This study will provide clinically meaningful and useful data in the armamentarium of a very complicated treatment regimen.
Please describe any other information you would like to share that supports your nomination.	Recruitment and retention in mental health studies can be a challenge. However, in order temper the challenge, we would include 9 top academic centers across the US who specialize in pediatric psychiatry care.