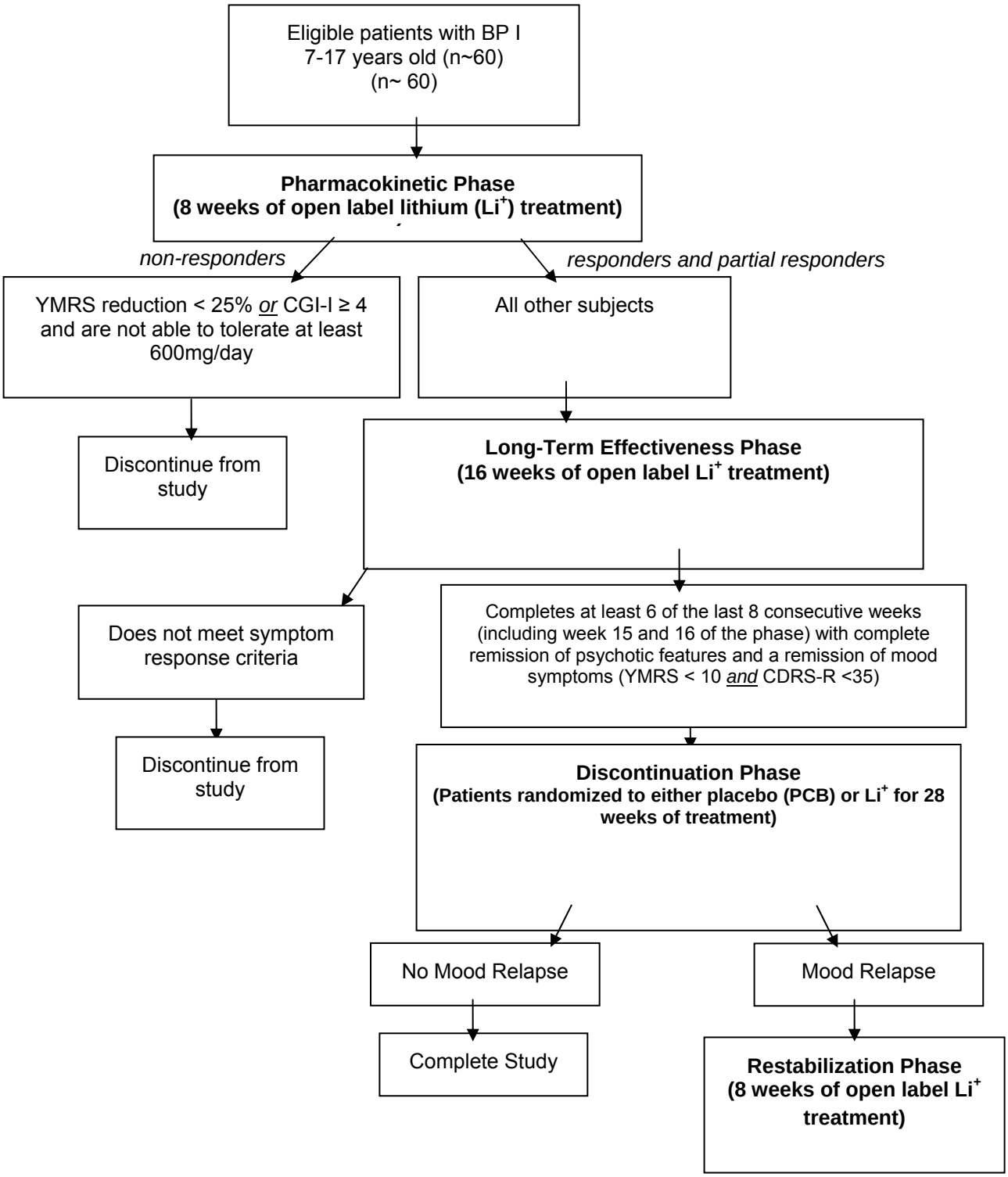
Eligible patients with BP I
7-17 years old (n~60)
(n~ 60)
Pharmacokinetic Phase
(8 weeks of open label lithium (Li+) treatment)
non-responders
responders and partial responders
YMRS reduction < 25% or CGI-I ≥ 4 and are not able to tolerate at least 600mg/day
All other subjects
Discontinue from study
Long-Term Effectiveness Phase
(16 weeks of open label Li+ treatment)
Does not meet symptom response criteria
Completes at least 6 of the last 8 consecutive weeks (including week 15 and 16 of the phase) with complete remission of psychotic features and a remission of mood symptoms (YMRS < 10 and CDRS-R <35)
Discontinue from study
Discontinuation Phase
(Patients randomized to either placebo (PCB) or Li+ for 28 weeks of treatment)
No Mood Relapse
Mood Relapse
Complete Study
Restabilization Phase
(8 weeks of open label Li+ treatment)