**START**

PI receives approval from their institution’s IRB for study amendment.

Amendment Approval Process NOTE: Approval of study amendment(s) may take 2 to 4 weeks.

**STEP 2A**

Review by HSRC Admin Team (1 to 2 weeks)

**STEP 2B**

HSRC Admin may request further info and/or missing documents from PI. (1 week)

**STEP 3**

**2nd** level review by DMH Data Security & Privacy Officers (1 to 2 weeks)

**STEP 1**

Submit Request for Amendment Form, edited HSRC Application, and all supporting documents to DMH HSRC.

**Changes requiring a Request for Amendment Form be completed:**

* Change in protocol (design, methods, procedures, etc.)
* Change in currently approved consent/assent forms
* Change in data collection tools
* Change to number of participants and/or selection criteria
* Change in recruitment materials (flyers, brochures, emails, compensation, etc.)
* Change in study materials (surveys, questionnaires, etc.)
* Addition of study site(s)

**FINISH**

 If all requirements are satisfied, approval of study amendment is granted.