# **Amendment Approval Process**

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

# **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)

# **START**

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

### STEP 1

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

### STEP 2A

Review by HSRO Admin Team (1 to 2 weeks)

#### STEP 3

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

#### FINISH

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

# STEP 2B

HSRC Admin may request further info and/or missing documents from PI.

(1 week)