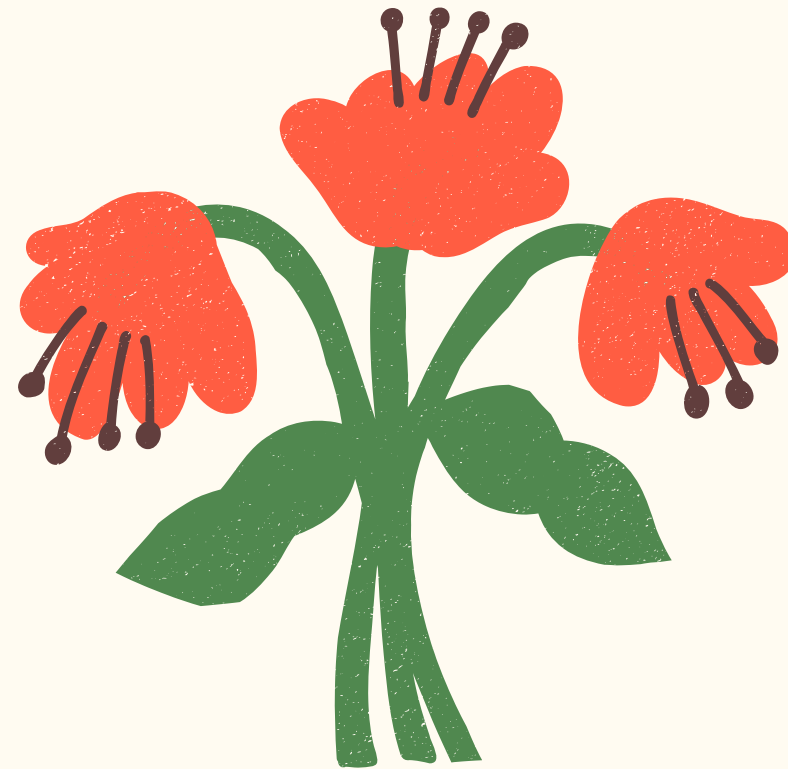


# REGULATORY SUBMISSIONS & TRACKING

JOHNS HOPKINS CENTER FOR INDIGENOUS HEALTH APRIL 17, 2025



# TRACKING GOAL(S)

Everyone on the study team stays INFORMED on the status of IRB approvals AND they know where to look to see where things are at

Status =

- In progress (submission is being worked on)
- Submitted (date)
- Review outcome:
  - tabled with concerns/questions
  - approved with concerns/questions
  - approved
- Final approved docs - where are these filed?

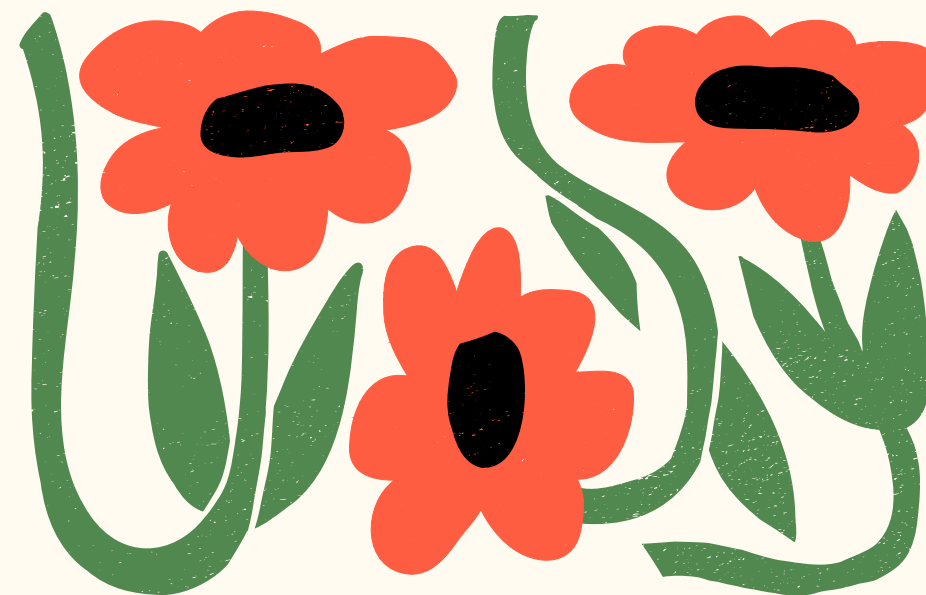


# WHO DO YOU NEED APPROVAL FROM?

## Which Research Boards oversee your project?

(Where do you work, who/where are your participants?)

- IRB(s)?
- Department(s) of Corrections?
- Tribal community IRBs/Research Review Boards?



# TEAMS FILING AND ORGANIZATION

## STUDY TEAM

- **IRB (Channel)**
  - **IRB**
    - In Progress folder
    - Completed folder
  - **RRB**
    - In Progress folder
    - Completed folder
  - **Other Regulatory**
    - **DOC RRC**
      - In Progress folder
      - Completed folder

**FINAL APPROVED  
DOCUMENTS  
FILED HERE**

## STUDY TEAM

- **FORMS IN USE (Channel)**
  - **Consent Forms**
  - **Recruitment materials** (templates of flyers, invite letter, recruitment scripts, etc.)
  - **Research Plan** (protocol)
  - **Surveys**



# EXAMPLE: REGULATORY TRACKING

1

Determine and record "requirements"  
(= when are things DUE)

- **IRB** - Continuing review must be submitted AT LEAST X weeks prior to study expiration.
- **RRB** - Continuation request must be submitted AT LEAST X month prior to study expiration.
- **NIRB** - Continuing review must be submitted AT LEAST X days prior to study expiration.
- **DSMB** - Currently meets every X months.
- **CT.gov** - requires verification every X months (at least)
- **DOC** - Progress reports required every X months, submit AT LEAST X WEEKS prior to X-month due date

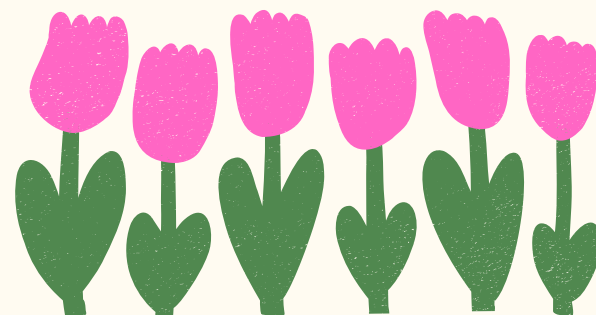


# EXAMPLE: REGULATORY TRACKING

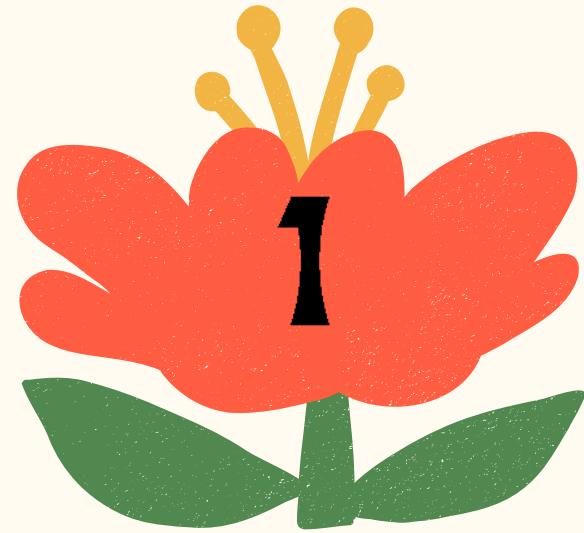
## 3

### Create Calendar entries

- **PROMPT DATE** = **1 month before a submission due date** create a calendar entry to **"PROMPT"** you to begin working on the submission
  - include the actual submission due date and the approval expiration date (if applicable) in the calendar prompt
- **SUBMIT DATE** = **2-5 days before a submission is due** create a second calendar entry **"SUBMIT"** to remind you that this submission is due in x number of days.
  - include the actual submission due date and the approval expiration date (if applicable) in the calendar prompt
- **CALENDAR ENTRIES:** Include PI on calendar invite as "FYI"

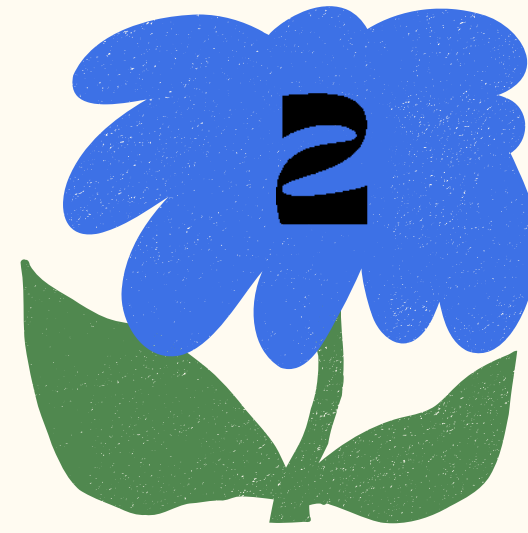


# WORKFLOW OVERVIEW



**Need for for an IRB submission has been identified:**

- Initial submission
- Amendment
- Continuing Review
- Event Report



**Create NEW folder within "In Progress"**  
**WORK on the submission**

- What documents need to be submitted/revised?
- Amendment: Pull the current approved docs for tracking edits
- Continuing Review: Review what you submitted last time
- Work with team on documents

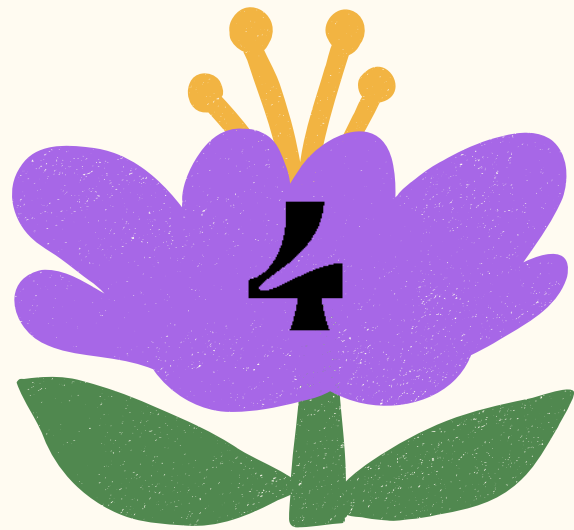


**Ready to submit**

- SAVE any working docs with comments or edits in a "Archive" or "Notes" folder
- SUBMIT to IRB
- FILE submitted docs within a "Submitted" folder (include emails sent to IRB )

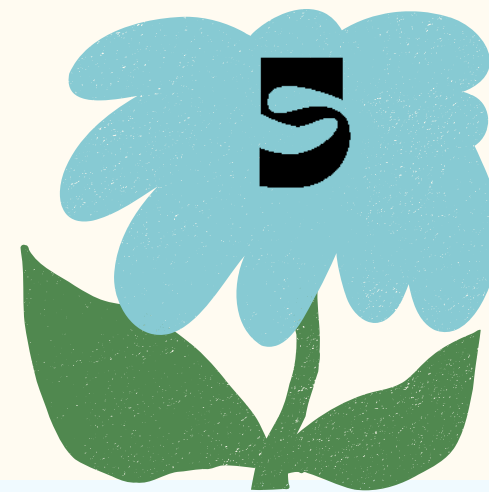


# WORKFLOW CONT'D



**PAUSE: Everything just hangs out in the "In Progress" folder until the IRB review outcome:**

1. tabled with concerns
2. approved with concerns
3. approved



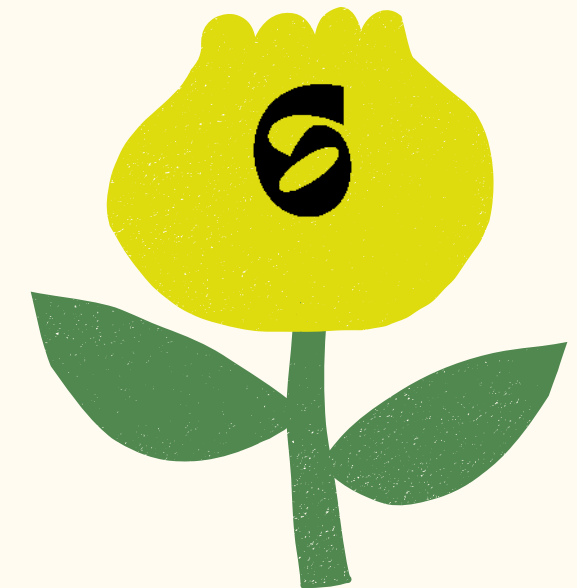
## FILE Review Outcome

### CREATE new folders as needed

**1 & 2** - Additional actions required so everything stays in the "In Progress" folder.

> CREATE new folder under original folder to file responses and any new tracked/clean forms for re-submission

**3** - FILE Approval within the submitted documents folder and MOVE everything to "Completed Submissions"



## Wrap up

- FILE all newly approved documents into the "Forms in Use" folder (removing old versions if applicable)
- COMMUNICATE to your team that final approval has been received and summarize next steps...
- UPDATE tracking table



# ALSO IMPORTANT: TEAMS TASKS

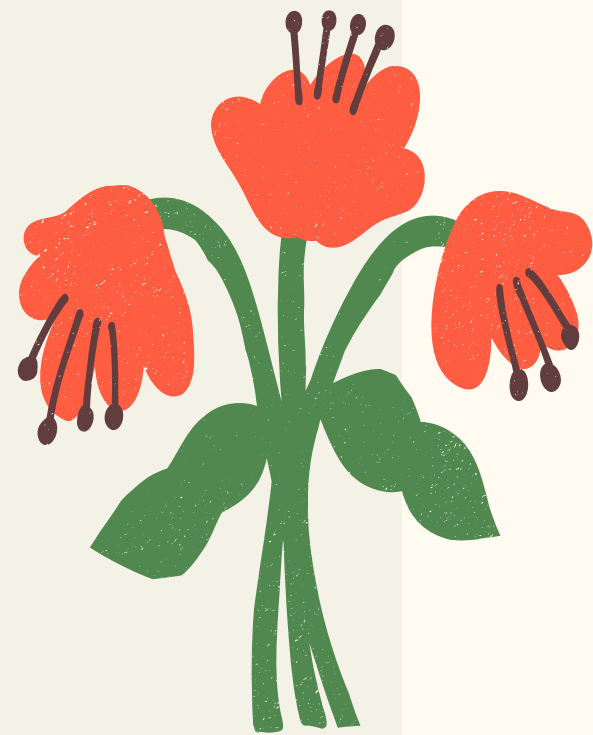
In addition to the tracking table, calendar reminders, document filing and organization, it's helpful to also create a task for each IRB submission.

## **Example:**

“Submit Phase 3 Amendment (IRB)”

### **Task Checklist:**

- ☐ Outline Amendment changes (what needs to be edited, tracked, created, etc.):
- ☐ Draft Amendment documents:
- ☐ Request help from study team for review/edits (as needed):
- ☐ Connect with PI for specific questions/clarifications (as needed):
- ☐ Enter Amendment submission (including uploads) into Phirst:
- ☐ Prompt PI (example next slide) that Amendment is ready to submit in Phirst:
- ☐ Amendment Submitted:
- ☐ IRB review outcome/acknowledgement received:



**COMMENTS/QUESTIONS?**

