Work Flow for Data Sharing and Research Collaborations

This page describes the work for for the DataSharingResearchCollaborationSystem

Work Flow 1/ Web Page 1 - Log collaboration/study

This work flow begins when an institution contacts NeuroPace about a collaboration project/study. These topics are discussed at the weekly Research Meeting (Weds 12:30p pacific) or via email to determine whether the collaboration is given a green light (approved) or red light (rejected) or can be voided (due to a mistake). The collaboration project/study and result are tracked here.

Gather audit trial so we know who changed what and when.

Gather this information:

- **Entry Date** (auto - maybe just audit trail)
- **Entered By** (auto - maybe just audit trail)
- **Institution** (drop down + other)
- **Institution Contact** (free text)
- **PI** (optional, free text)
- **Reason for Collaboration** (drop down)
- **Description** (free text)
- **Category** (drop down + other)
- **Date Needed** (optional)

After review, record decision:
Set **Status** to:

- If given Green Light, then Status = "Pending" and move to Work Flow 2 / Web Page 2.
- If given Red Light, then Status = "Rejected/Void", and document why. (free text)

Work Flow 2 - Obtain details regarding collaboration/study, contracts, budget, regulatory documentation and data sharing

Web Page 2 - Collaboration/study details

Record this information:

- **NeuroPace Contact** (drop down + other)
- **Study Type** (drop down)
- **Study Identifier** (drop down)
- **Study Title** (free text)
- **Study Risk Level** (drop down - may not know this until later)
- **Single- or Multi-Center** (drop down - may not know this until later)
- **Data Share Type** (drop down + other)
- **Data Sharing Method** (drop down + other)
- **Data Set Description** (drop down + other)
- **PHI Present** (drop down)
- **Research Accessories Needed?** (drop down)

After **Data Share Type** is entered, set the following:
Data Sharing Language:
Data Sharing Language indicates where the legally required data sharing language will reside.

- If **Data Sharing Type** = "NeuroPace Sponsored", then **Data Sharing Language** = "NeuroPace Protocol/ICF"
- If **Data Sharing Type** = "Investigator Initiated", then **Data Sharing Language** = "Institution Protocol/ICF"

Research Accessories Language:

Research Accessories Language indicates where the legally required research accessories language will reside, if applicable.

- If ***Research Accessories Needed?*** = "No", then ***Research Accessories Language*** = "N/A"
- If ***Research Accessories Needed?*** = "Yes" and ***Data Sharing Type*** = "NeuroPace Sponsored", then ***Research Accessories Language*** = "NeuroPace Protocol"
- If ***Research Accessories Needed?*** = "Yes" and ***Data Sharing Type*** = "Investigator Initiated", then ***Research Accessories Language*** = "Institution Protocol"

Web Page 3 - Contracts and financials

Record this information:

- ***Funding Source*** (drop down)
- ***Compensated by NeuroPace?*** (drop down)
- ***Consultant to NeuroPace?*** (drop down)
- ***Contract Needed?*** (drop down)
- ***Budget Needed?*** (required/editable)

If ***Contract Needed?*** = "No" and ***Budget Needed?*** = "No", then ***Contract Status*** = "N/A" and move to Work Flow 3, otherwise ...

Record Contract Status
Contract Status:

- ***Contract Approval Date*** (date field)
- ***Contracting Notes*** (free text)

- If ***Contract Status*** = "Not Completed", document why, date CMO gave approval, then move to next work flow
- If ***Contract Status*** = "N/A", then move to next work flow.

Note that ***Contract Status*** indicates whether NeuroPace needs and has executed a Contract.

Note that in rare cases we may want to progress to the next flow even though the ***Contract Status*** = ***Not Completed***. In that case we should document: (a) why and (b) approval from the CMO.

Work Flow 4 - Confirm required legal language is present in documentation (e.g. protocol, ICF)

This work flow begins when contracting, if needed, is fully executed and the study protocol (e.g IRB, FDA) and IRB consent documents are in process. At this point we may be able to move forward quickly or may need to work with the institution to ensure appropriate language exists for data sharing and when needed, research accessories (this can take from weeks to months).

Gather this information:

- ***Protocol Coverage for Research Accessories?*** (required)
- ***Protocol Coverage for Data Sharing?*** (required)
- ***ICF Coverage for Data Sharing?*** (required)
- ***IRB Approval Date*** (required)
- ***IRB Expiration Date*** (required)
- ***Data Sharing/Research Accessories Notes*** (optional/editable)

Once this information is entered, set ***Data Sharing Status***
Data Sharing Status (Approved; Cancelled; Completed; Denied; On Hold; Under Review; Void)

- ***Data Sharing Status***
- ***Date Data Sharing Status Changed*** (auto)
- ***Data Sharing Status Changed by*** (auto)

Data checks

- If IRB Expiration Date is less than 30 days away, send email trigger to Julie, Nick, Tom
- If IRB Expiration Date is less than or equal to current date, send email trigger to Julie, Nick, Tom AND change ***Data Sharing Status*** to "On hold"

Reports

- **Project by "Collaboration status".** Helpful for reviewing new projects or reviewing what projects have been brought forward and denied in the past.
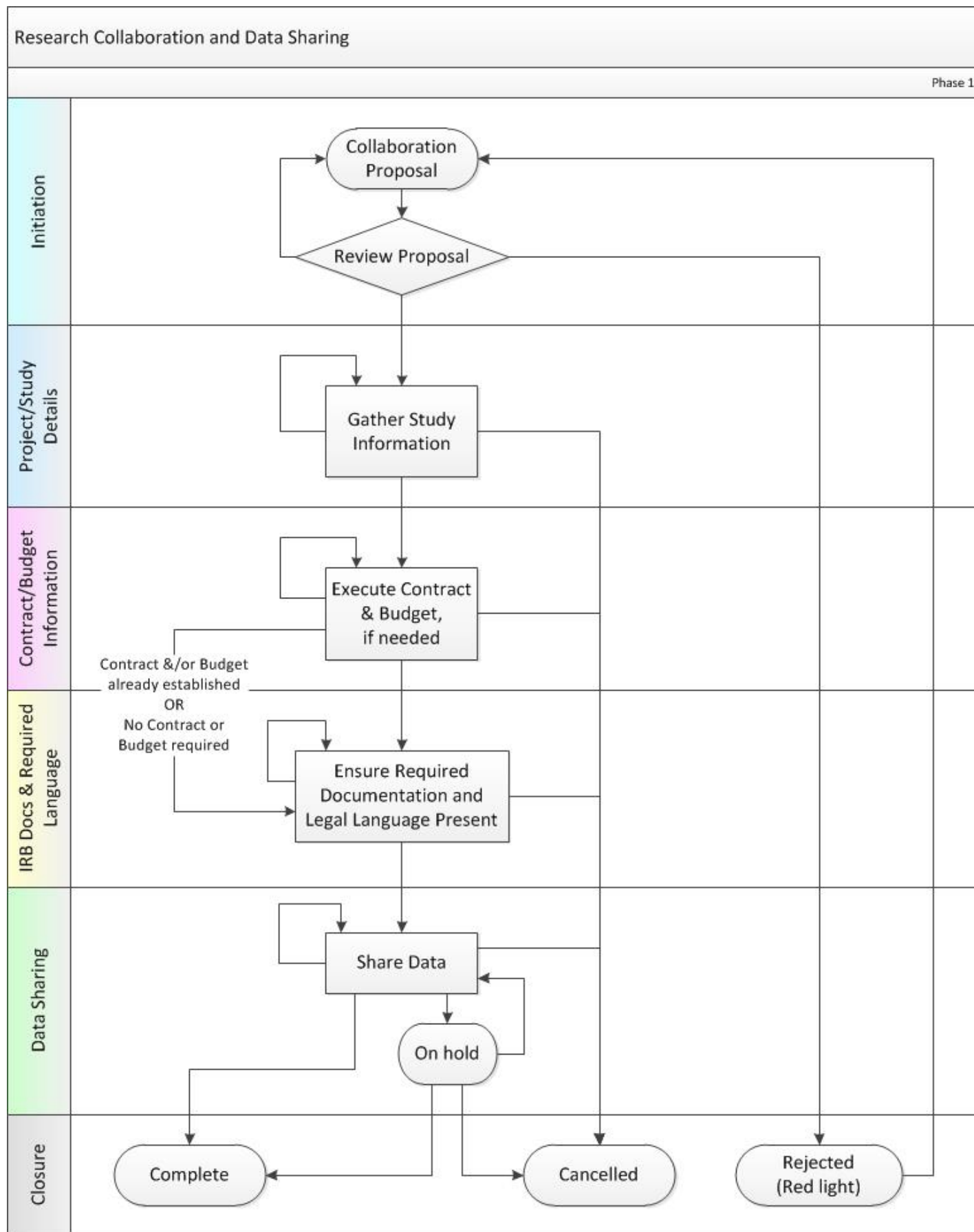
If denied (red light) then we can stop there.

Comments

Status (Approved; Cancelled; Complete; On Hold; Pending; Rejected/Void?) When changed always record who/date (or maybe just audit trail)

- If "Approved", the data sharing is allowed.
- If "Cancelled", document why, then done. (free text)
- If "Complete", document why, then done. (free text)
- If "On Hold", document why, then hang until correction is made. (free text)
- If "Rejected/Void", document why, then done. (free text)

Workflow diagram

Research Collaboration and Data Sharing

Phase 1

Initiation

Collaboration Proposal

Review Proposal

Project/Study Details

Gather Study Information

Contract/Budget Information

Execute Contract & Budget, if needed

Contract &/or Budget already established

OR

No Contract or Budget required

IRB Docs & Required Language

Ensure Required Documentation and Legal Language Present

Data Sharing

Share Data

On hold

Closure

Complete

Cancelled

Rejected (Red light)

Pages linking to DataSharingResearchCollaborationWorkFlow:

- DataSharingResearchCollaborationSystem

Use Chrome Extension Local Explorer to open local file & folder links.

Attachments (4)   *Last modified on Apr 7, 2017 2:48:54 PM*

- DataSharingResearchCollaborationSystem

Use Chrome Extension Local Explorer to open local file & folder links.