

**PURDUE**  
UNIVERSITY

**HRPP IRB**

**DESIGN DOCUMENTATION**

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# Team Overview

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# Project Overview

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## HRPP AND IRB

The **Human Research Protection Program (HRPP)** ensures that all human subjects research conducted by faculty, staff and students of Purdue University is conducted ethically and in a manner that promotes the protection of the rights and welfare of human subjects.

The **Institutional Review Board (IRB)** is a type of committee used that has been formally designated to review, approve, and monitor biomedical and behavioral research involving humans.

## OVERVIEW AND PROBLEM

The processing of IRB submissions is time consuming, involves multiple steps, and sensitive to human error.

This project will focus on understanding the IRB submission process from the receiver side. The HRPP depends on both paper and electronic processes and records. The database and online submission system is CoeusLite. The online submission system allows investigators to submit to the IRB electronically, and to track the status of the protocol. Because documents can be removed from Coeus, paper files must also be kept to meet regulatory requirements.

## PROJECT GOAL

The goal of this project will be to **understand the users** on the receiver side of the IRB submission process and to **provide research-based suggestions for best practices** to create a more efficient and effective workflow.

# Understanding the Users

surveys | interviews | observations

# **Understanding the Users**

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A big concern that was mentioned in our kickoff meeting was the issue of the review staff doing their processes differently. This would result in different outcomes. We wanted to understand how each individual worked and determine what the best practice is. Luckily, we have a small group of users that will allow us to reach out to all of them: one intake (the other is out sick), four part-time students and four analysts (one is new).

Below is a short visualization of the relationship between the different users and what process the proposals go through.

## **PRINCIPAL INVESTIGATOR (PI)**

The PI submits a proposal for research to the IRB. Their primary goal is to get IRB approval for their proposal. PIs tend to have a general awareness of the guidelines and ethical requirements surrounding human subject research, but not in depth subject matter expertise. Their understanding of the review process itself is minimal.

## **INTAKE STAFF**

There are two full-time intake staff members, who are supported by three part-time students. The full-time employees are responsible for receiving the electronic submission, reviewing the submission for completeness, working with PIs to make submission corrections to achieve completeness, making administrative changes to the database, printing the submission and setting up the paper study file, routing the submission to an analyst for review, and recording their activity in a data capture system.

The part-time students are responsible for specific tasks, ranging from office support such as refilling the copier and filing, to executing specific administrative tasks.

## **ANALYST**

There are three full-time, soon four (starting early February), analysts, who are supported by one part-time student. The analysts review the paper files routed by the intake personnel, make additional entries and notes in CoeusLite, and analyze proposals to determine whether it is IRB “approvable.” Proposals (with or without revision request comments) are routed for expedited review or for full board review.

## **REVIEWER**

There are 2 main IRB committees (Social Science (SS) and BioMedical (Bio)). Each committee meets once each month to review studies that do not meet the criteria for expedited review. The deadline for protocol submission for full board review is 2-weeks before the meeting date.

# Understanding the Users

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For our initial user research, we sent out surveys, conducted interviews, and did observations on our users. The following pages will show our protocol for each method we chose.

## SURVEYS

Surveys were conducted to garner initial information about the IRB workflow from the perspectives of the intake staff and analysts.

Four members of staff were surveyed, two intake staff and two analysts. Each were asked a series of questions, such as how their time is spent and what they like and dislike about their workflow. From this, it is apparent that both user types use Coeus extensively, and interact with each other and principal investigators regularly. It is also clear from the responses that Coeus is an often unintuitive program and comes with its own set of challenges added to the workflow.

## INTERVIEWS AND OBSERVATIONS

Following surveys, interviews and observations were conducted to further our understanding of each user's workflow, pain points, and other information regarding the IRB process. Interviews and observations worked hand-in-hand in a sense that we would ask them questions as we observed them.

The processing of IRB submissions is time consuming, involves multiple steps, and sensitive to human error. Protocols vary wildly, and if documents are not written and uploaded correctly the time to process them may quadruple. Documents are uploaded, printed, scanned, and comments are added both on paper and on Coeus. With this, users have different means of creating and accessing information such as comment libraries and email templates. Staff often interact with principal investigators, helping them with topics ranging from Coeus help to specific questions regarding their protocols.

## USERS

1 Intake

4 Analysts

- Experience ranging from a couple months to 5+ years

1 Part-Time student worker

All women

Users walked through their processes, from the time they get a protocol to when it leaves their hands. These steps from the intake side included the receipt of a protocol in Coeus, printing all required documents, going through a checklist, and choosing to send it back or deliver it to an analyst. As it gets to the analyst, they review the file on paper while making personal notes, commenting on the protocol in Coeus, filling out and scanning a review sheet to upload and send out for review. Within each step lies several

# Understanding the Users

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smaller steps and challenges along the way, many with room for human and computer error. Documents can be missing from files, scanners may skip pages unintentionally, and whole protocol folders can be misplaced. Personal organization seems a necessity for the review of protocols- with protocols categorized often by first in, first out, but with occasional exceptions for protocols that may be quicker or closer to a deadline.

## PROTOCOL

We set observation goals to establish what we are looking for when we talk to our users. We would essentially tell them to go the steps it takes to review a protocol. If the observations didn't naturally accomplish our goals, we would ask the question indirectly. To set up, we let them know to say what they're thinking while going through the process. We also asked for permission to record voice, video, and take pictures. Here are our goals:

- Clarify user role
  - When/why they interact with other users (intake, committee, principal investigator, etc.)
- Walk through typical tasks
  - Most common, most time consuming, inefficient
  - What extra tools (email, Microsoft word, etc.) are used in the process
  - Examine the differences between paper/CoeusLite process
    - Time, ease of use, mistakes made
  - Discuss where user error can occur
    - What contributes to the error(s)?
  - Cover any additional questions from the survey or interview process

## INSIGHTS AND QUOTES

- “[The review process] **takes longer now**, there’s **no support** for Coeus.”
- “I was so excited when I knew we were going to launch the electronic system... **but it's just been a disaster.**”
- “We make sure that before we give it to a chair, that all the documents that **need to be in PDF format** are **properly labeled** and **changed.**”
- “Language that we use quite a bit... I save them in my drafts (**Outlook Mail**)”

One prominent insight shared from across intake and analysts alike is inconsistencies in PI submissions. Often, PIs are unaware of all of the IRB’s requirements and how they apply to their particular protocol(s). With this, mistakes are often made by PI leading to increased numbers of protocols being sent back to investigators for revision. Often, as with any process this takes time, investigators are left with little communication over an extended time due to the IRB process and the investigator mistakes lengthen the time they spend in contact with the IRB.

One concern brought about in the observations is the lack of security with the Coeus system. Coeus has often been known to be missing forms, and protocols have the potential to be deleted from the system with little recourse for their recovery. This has

## **Understanding the Users**

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caused the office to retain paper copies of protocols and all associated information about them. These paper copies travel around the office, and due to the office's reliance on paper files they often need to be tracked down in order to access the files and their content. Tracking these documents and relevant data (such as the type of review or the time it has taken to be processed) is a function that is lacking from this system which leads to some level of difficulty in reporting and tracking IRB data. One other feature which the system cannot manage is the creation and sending of notices to PI such as expiration notices. This task falls onto the intake staff.

Checklists for intake and analyst processes have been created with the goal of reducing error and providing for a more concrete set of requirements against which protocols can be measured. This has been shown helpful in training new members of staff as well as creating a helpful guide with which to determine next steps in protocol review. However, some concerns are raised in that review of this checklist could extend the time it takes to complete a pre-review of a protocol, as often analysts and intake staff face protocols which are wildly different and may not use all of the steps listed (or may require more).

# Personas and Scenarios

## **Personas and Scenarios**

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The purpose of personas and scenarios is to represent user goals and behaviors. The descriptions and attributes of these personas derive from the user interviews and observations we did with the IRB staff. We created a total of three personas that will be shown in the next three pages: one intake and two analysts.

# Intake Persona

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The full-time employees are responsible for receiving the electronic submission, reviewing the submission for completeness, working with PIs to make submission corrections to achieve completeness, making administrative changes to the database, printing the submission and setting up the paper study file, routing the submission to an analyst for review, and recording their activity in a data capture system.

## BACKGROUND

- Female
- Has been at Purdue IRB for a few years

## GOALS

- Turn around a protocol within 14 days
- Minimize rejected protocols
- Catch errors in submissions



## PAIN POINTS

### Coeus

- Frustrated that PIs don't always submit everything or label correctly
- Doesn't trust Coeus because anyone can delete files
- Coeus team won't set up group email

### Workflow

- Doesn't like rejecting proposals because it delays process and takes too long
- Paper files can easily be lost or hard to find, but analysts want hard copies of everything, so changes must be made into multiple copies
- Checklist reduces error but adds time to workflow
- Usually 2 days behind

## RESOURCES

### Computer

- Coeus admin, Coeus Lite
- Email notifications from Coeus
- Adobe Acrobat to view and edit PDFs
- Word document - list of comments (common mistakes) for feedback when rejecting proposals

### Paper

- File containing hard copies of the detailed summaries of a proposal and its attachments, all revisions
- Checklist - hard copy of items that need to be completed before the protocol goes to the analyst
- Sends hard copies of all protocols to review board members through campus mail
- Printed manual on how to use Coeus with handwritten notes

# Analyst Persona

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The analysts review the paper files routed by the intake personnel, make additional entries and notes in Coeus Lite, and analyze proposals to determine whether it is IRB "approval." Proposals (with or without revision request comments) are routed for expedited review or for full board review.

## BACKGROUND

- Female
- Has been at Purdue IRB for 8 years

## GOALS

- Improve on time efficiency
- Strengthen Stakeholder relationships

## PAIN POINTS

The Principal Investigator:

- Analyst takes over the Intake's role for small issues
- If any questions are needed to be asked to the Principal Investigator, the analyst emails them
- Uploads the documents that are given by the Principal Investigator, into the Coeus Software



The Review Board:

- Preparing for The Full Board takes 2-3 weeks
  - Takes 16 hours prior to the meeting
  - Takes 8 hours to collect all data and documentation after the meeting
- When the protocols are sent to the virtual and nonvirtual reviewers, the process takes too long for the protocol to return

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Computer

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# Analyst Persona

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## Background/Demographics:

- Female
- Has been at Purdue IRB for about one year



## Goals:

- Would like to work in a new methodology
- Broaden own skills by using new techniques

## Pain Points:

- There are too much printing and scanning when the reviews need to be sent out
- Goes back to The Coeus Software to make sure that it doesn't have missing pages
- Most of the time, papers are missing in the files

## Frustrations:

The Principal Investigator:

- Having Walk-Ins every Tuesday causes her to review less protocols
- Has to respond to students that email asking questions about the IRB

The Review Board:

- Files are sent via linked to a software called FileLocker
- Always has to rename the PDF's

## RESOURCES

Computer

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Paper

- File containing hard copies of the detailed summaries of a proposal and its attachments, all revisions
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# Competitive and Analogous Research

IACUC | iRIS

# **Competitive and Analogous Research**

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## **PURDUE IACUC**

The Purdue Institutional Animal Care and Use Committee (IACUC) submission system differs from that of the Purdue IRB in a few key ways. When a protocol is submitted to the IACUC, it is distributed in such a way that all members of the IACUC have access to the protocol, while a few members are directly designated to review the document. Primarily, these designated reviewers are the only ones to review the protocol, and the others are given the opportunity to view the protocol as a regulatory measure. The IACUC generally have a smaller influx of protocols submitted, and as such are able to process their volume of protocols at a quicker pace. Additionally, the IACUC has less administrative review, and many protocols are given directly to committee review once submitted by PIs. Protocols submitted to the IACUC are on average returned to the PIs for revision far less than IRB protocols.

IACUC uses the CoeusLite interface for the purpose of reviewing protocols, and though they keep some paper files there is little trace of on-paper reviewing (including with Purdue non-affiliates who have been given a Purdue career account in order to access the CoeusLite system for their reviews).

Other organizations within Purdue also use the Coeus system, such as for contracting purposes. Often these organizations use different tools within the Coeus system to accomplish their tasks. It is possible that further exploration into the coeus system and any underutilized features could yield positive results.

## **iRIS - TEXAS A&M IRB**

As part of the secondary research, the iRIS system used by Texas A&M was examined. The system's PI side serves a similar purpose to CoeusLite. Users fill out forms and upload documents which are later sent to the IRB for review. Each protocol submission appears to follow a step-by-step input of forms and documents with the ability to review a summary of this information as it has been entered. The iRIS system contains documentation on how to perform various actions within the system such as "How to Revise a Document including Check Out Check In steps" and "Submitting an IRB Application".

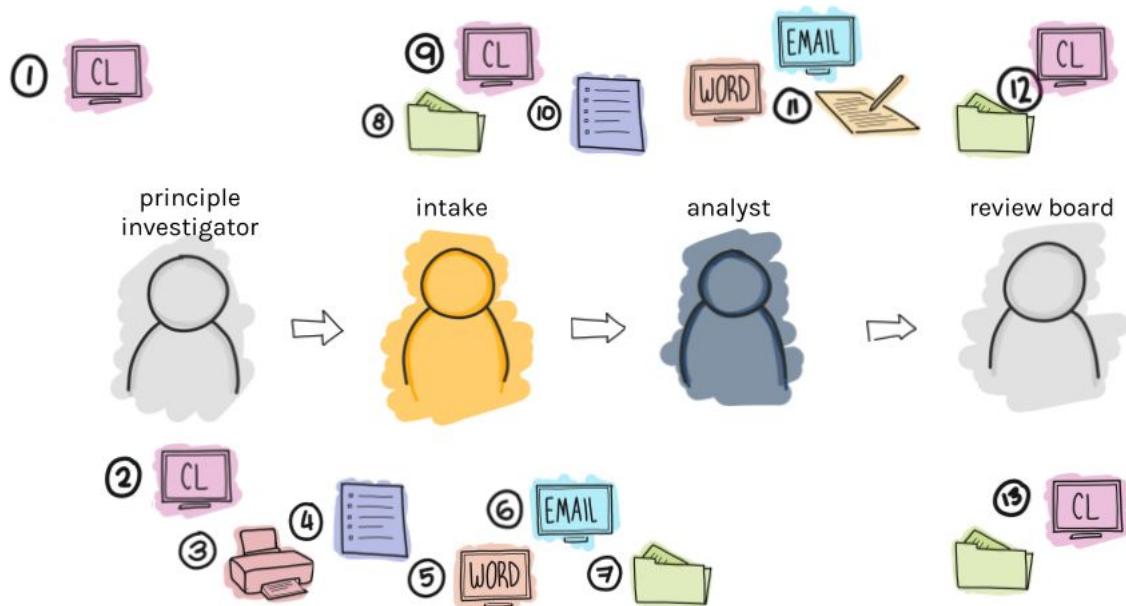
Overall, looking into the iRIS system, it showed some level of similarity with the functions of the CoeusLite system. It has a strong emphasis on providing resources for PIs to learn about the system and how best to submit protocols through it for not only the IRB, but the other organizations such as their IACUC. Ultimately this was an analysis from the PI side of the system and as such is somewhat outside of the scope of this project. However, it is evident from this that protocol submission is a complicated process regardless of the systems used, and the ability to communicate what an IRB is expecting through such a system is important.

# Task Flows

# Task Flows

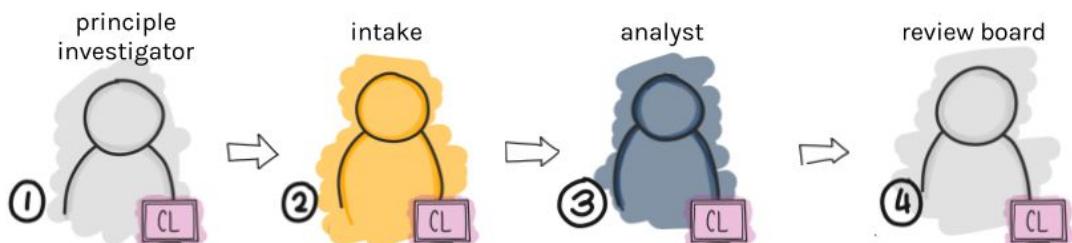
## IRB TASK FLOWS

### CURRENT TASK FLOW



Currently, the IRB workflow is very overwhelming and the staff has to go back and forth to get their job done. The principal investigator is the main person that starts the entire process. After it goes to the PI, the PI sends the proposal to the Intake so that they can review the proposal for completeness. However, if the proposal isn't complete, the Intake has to send it back the PI. This same workflow happens between the Intake and Analyst. After the Analyst's reviews the proposal, if there are issues with the paper, then it needs to be sent right back to the PI. When the PI reviews it and after they are done, then they send it back to the Analyst that last reviewed the proposal. The Analyst gets the proposal back, sends it to the review board, and then the review board sends it out to get a decision. However, if the decision is incomplete, they need to send it back to the analysts that reviewed it, and do the process all over again. It's quite a long and inconvenient process that the IRB staff has to go through.

### IDEAL TASK FLOW



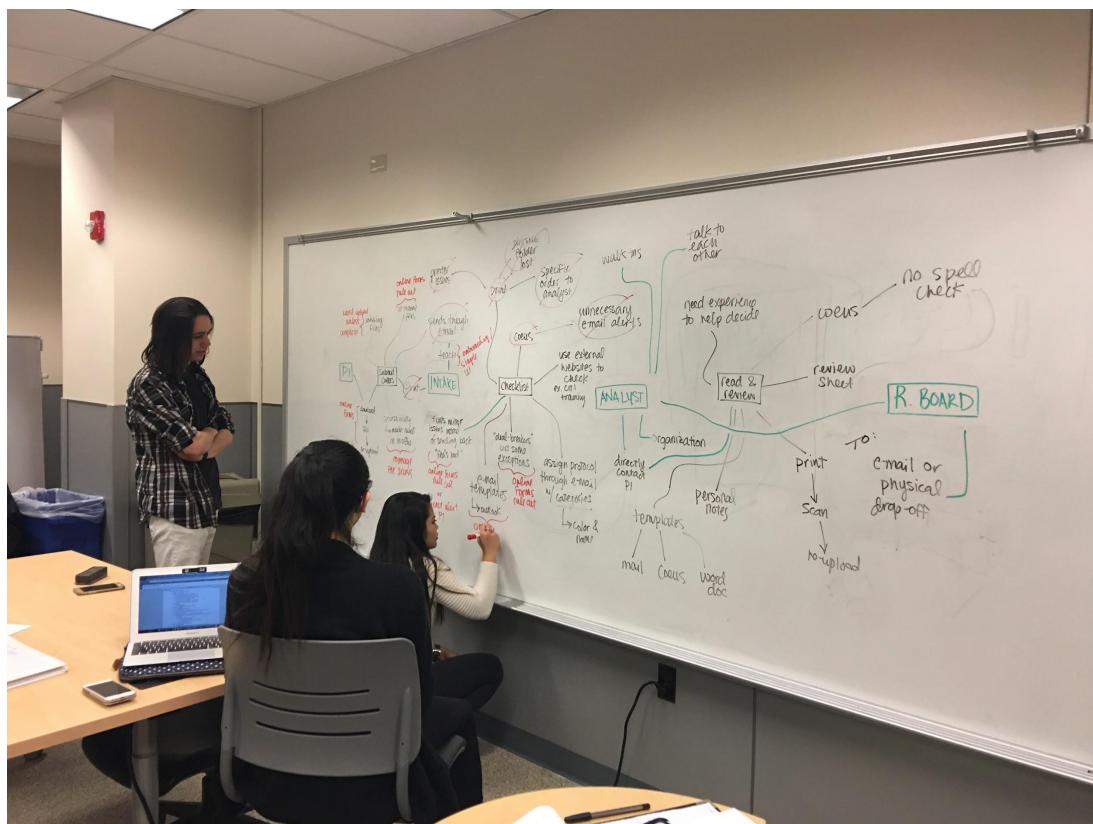
After visualizing the workflow that the IRB staff goes through, we thought it would be very helpful if there were no back and forth or errors happening during the task flow. For our ideal task flow that would work better would be a linear process where the IRB staff can go through every person without sending back the proposal over, and over again.

# Task Flows

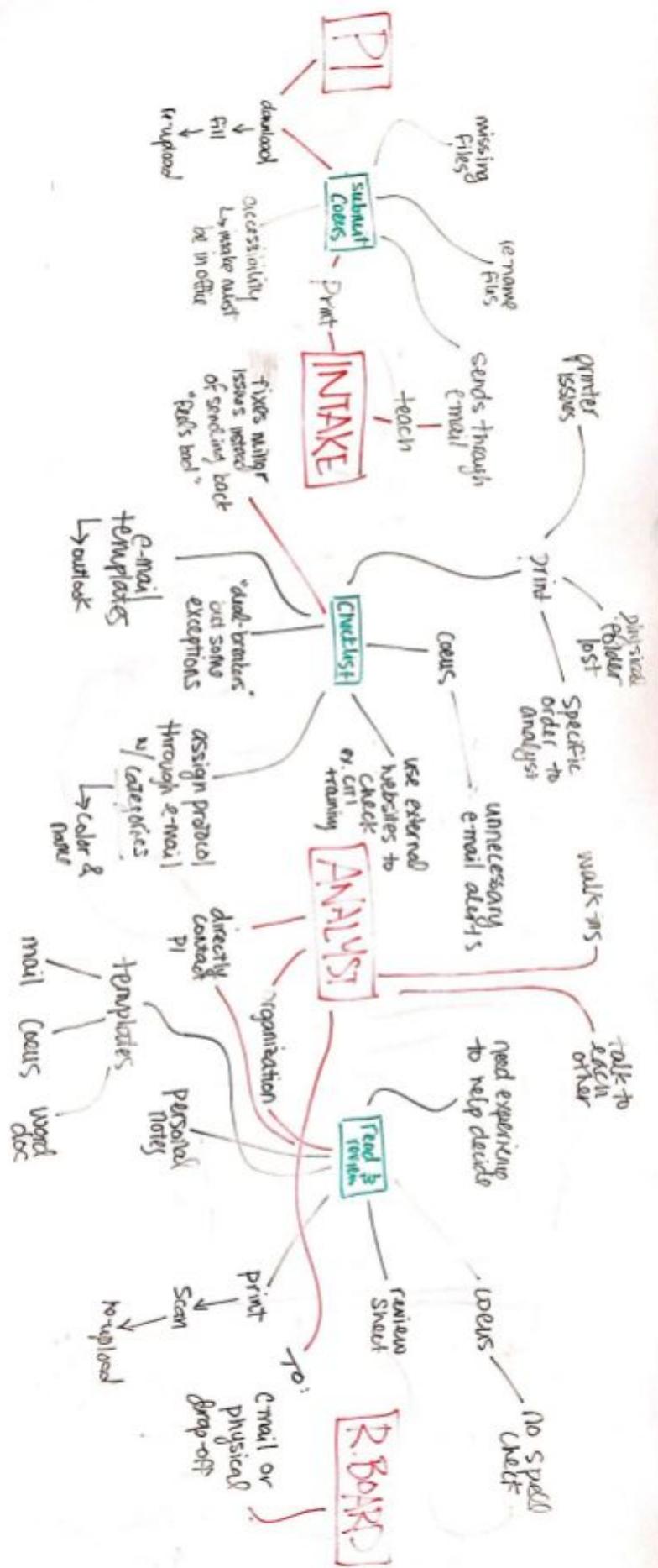
## IDEATION

During our process of ideation, we decided to combine all the IRB task flow problems into one huge task flow. We included the PI, Intake, Analyst, and Review Board (blue) because those are the only four users that we can help in the IRB. We started off by inserting each individual task (dark black) that they do during their process and within that task, we divided those into problems that they are having throughout their entire process. For example, when the PI submits a protocol through Coeus, to the the Intake, there have missing files. Shown on page 15.

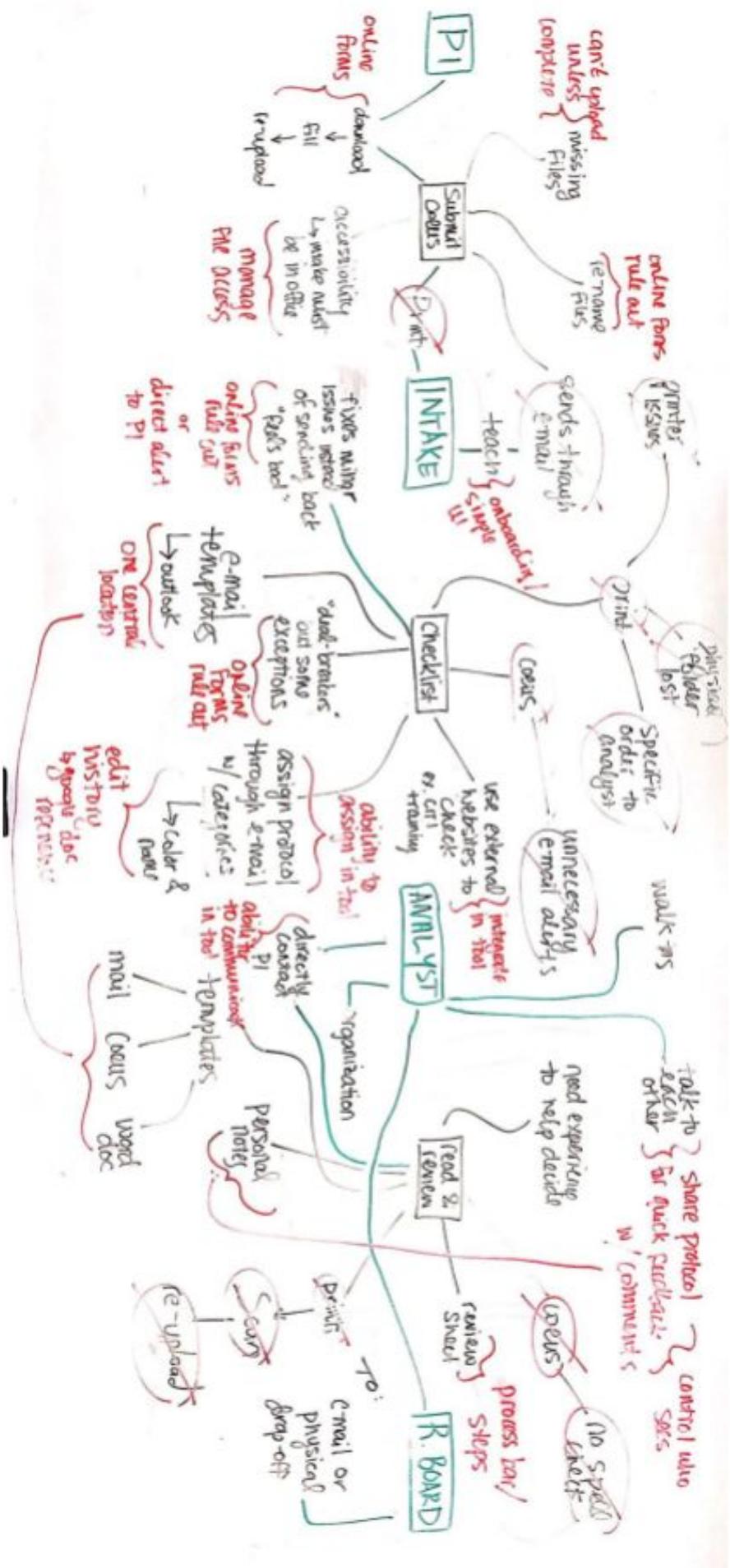
After writing it all down, we listed different ways on how we can eliminate that problem and suggest new ways on how to fix that certain problem. We used this technique throughout the whole process and seen where they are having problems and how we can fix those problems. After completing our ideation, we were overwhelmed with the problems (black), but excited about the solutions (red). Overall, we found many different ways on how to erase the problems that they are having and fixing them with new techniques/solutions. Shown on page 16.



# Task Flows - COMBINED TASK FLOW



# Task Flows - COMBINED TASK FLOW WITH CHANGES



# Ideation

rationale | sketches | feedback

## DESIGN RATIONALE

The insights from the user research led to the ideation of a desktop companion tool. Users showed and expressed a large volume of issues with the current technology solutions of the IRB workflow. Currently, the protocols handled by the IRB are stored and processed with the Coeus platform, using both its administrative and CoeusLite interfaces. The software was shown to facilitate user error from both the PI and IRB staff workflows, and the program itself is not a secure platform for storing this large volume of data reliably. As problems arise with Coeus, there is a limited amount of support the IRB can request or expect. The support is capable of small language changes and minor bug fixes, but larger issues with the system can be neglected or unaddressed. The rationale behind creating a new tool to work in tandem with Coeus and the IRB's other tools stems from the users and the IRB's need for a comprehensive, reliable, and efficient solution to their workflow.

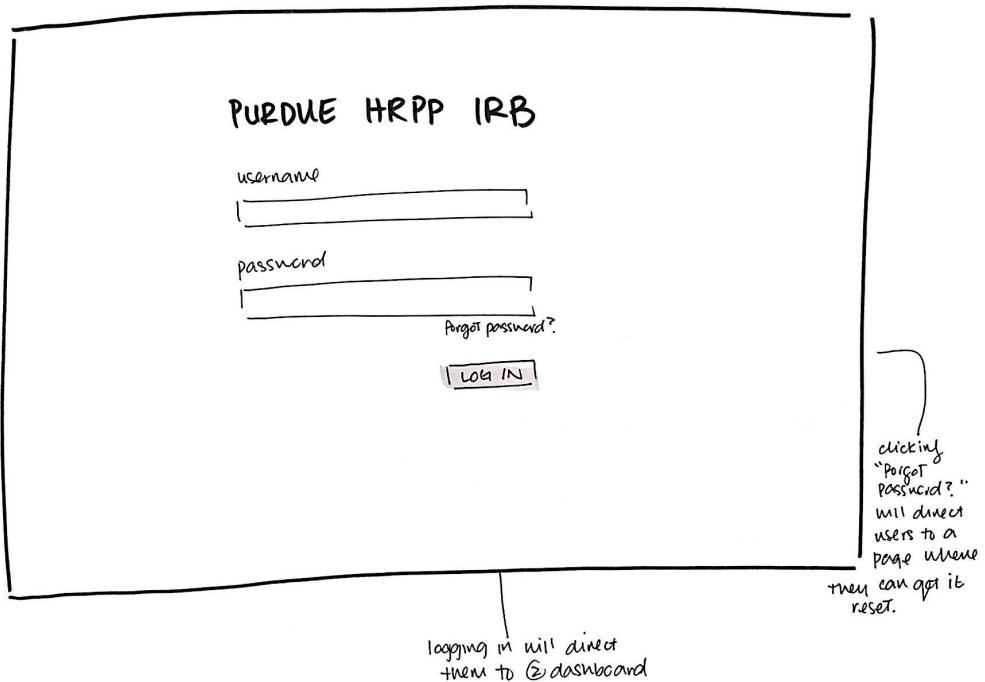
One other point of inefficiency is the use of many different tools to complete tasks within the IRB's workflow. These different softwares can cause issues with consistency, and taking the information from one software and entering it into another can be time consuming. In the recommendation for a new application, this is addressed by housing things such as comment template language in one central location. Additionally, this could reduce the need for paper files, in that a secure storage system would allow for better file security and a central location from which to review and comment on protocols internally.

# Ideation

## INITIAL SKETCHES

### ① HOME - login page

- IRB staff log-in set up beforehand



### ② DASHBOARD

A hand-drawn sketch of the IRB dashboard. At the top, there's a navigation bar with "HOME" and "name". Below it is a sidebar with "messages", "calendar", and "settings". The main area has a search bar for "PROTOCOL" and a "SEARCH" button. To the left, there's a date field and a note about searching by ID or name. The central part is a table with columns: ID #, PROTOCOL NAME, TYPE, STATUS, and ASSIGNED. A note says that clicking on column titles will change how you view the data on the table. The table contains 12 rows of protocol data. To the right, there's a "first last name position" section with "your stats" and a "VIEW more details" button. A note says that clicking the "name" button will bring up a pop-up menu. Another note asks how to search and sort protocols. A callout from the "VIEW more details" button says it will give more info on types of protocol finished, by user, average time it takes, etc. A note at the bottom right says "end #'s is total protocol" and "will increase as time goes".

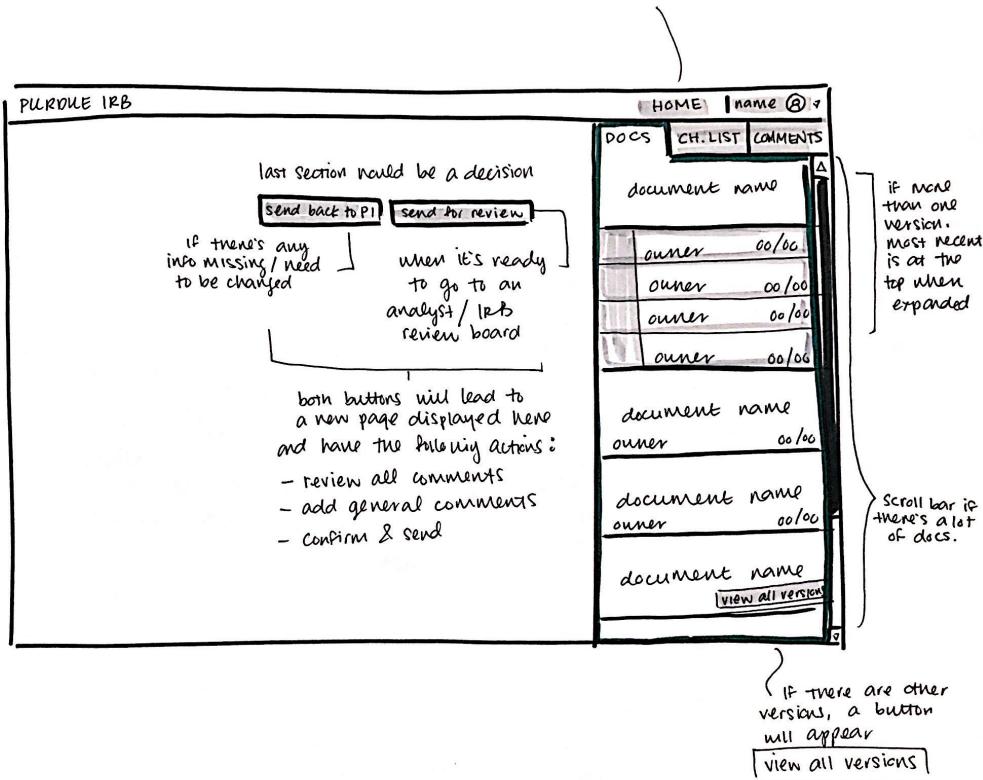
| ID # | PROTOCOL NAME | TYPE      | STATUS       | ASSIGNED |
|------|---------------|-----------|--------------|----------|
| 0000 |               | full      | needs review | name     |
| 0000 |               | full      | needs review | name     |
| 0000 |               | full      | intake       | name     |
| 0000 |               | full      | analyst      | name     |
| 0000 |               | exempt    | analyst      | name     |
| 0000 |               | exempt    | needs r.     | name     |
| 0000 |               | exempt    | needs r.     | name     |
| 0000 |               | exempt    | needs r.     | name     |
| 0000 |               | expedited | needs r.     | name     |
| 0000 |               | expedited | needs r.     | name     |
| 0000 |               | expedited | needs r.     | name     |
| 0000 |               | expedited | needs r.     | name     |

# Ideation

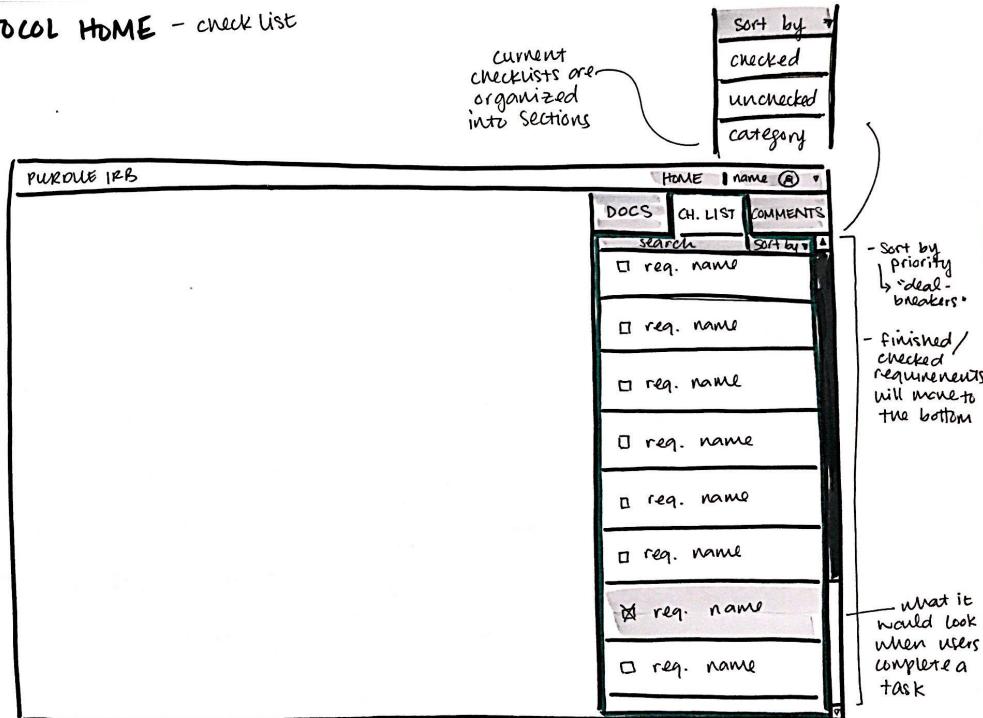
## INITIAL SKETCHES

### (3) a PROTOCOL HOME - Documents tab

### (2) DASHBOARD



### (3) b PROTOCOL HOME - check list

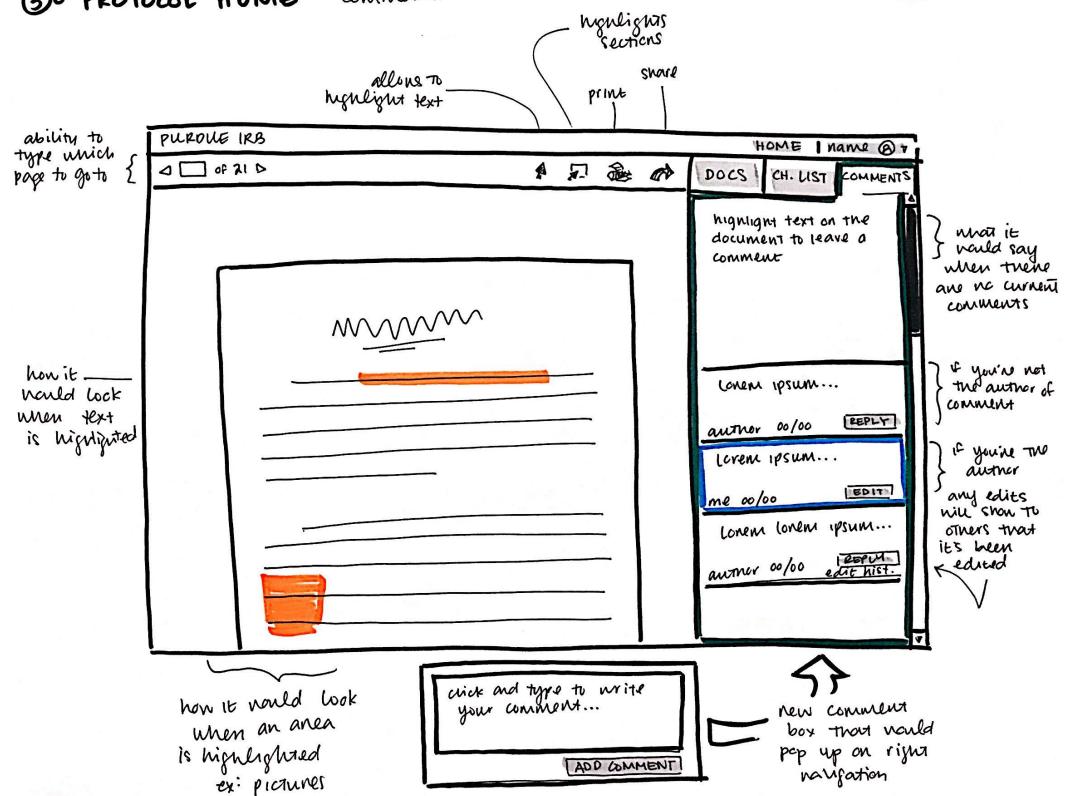


Would a search bar at the top be helpful?

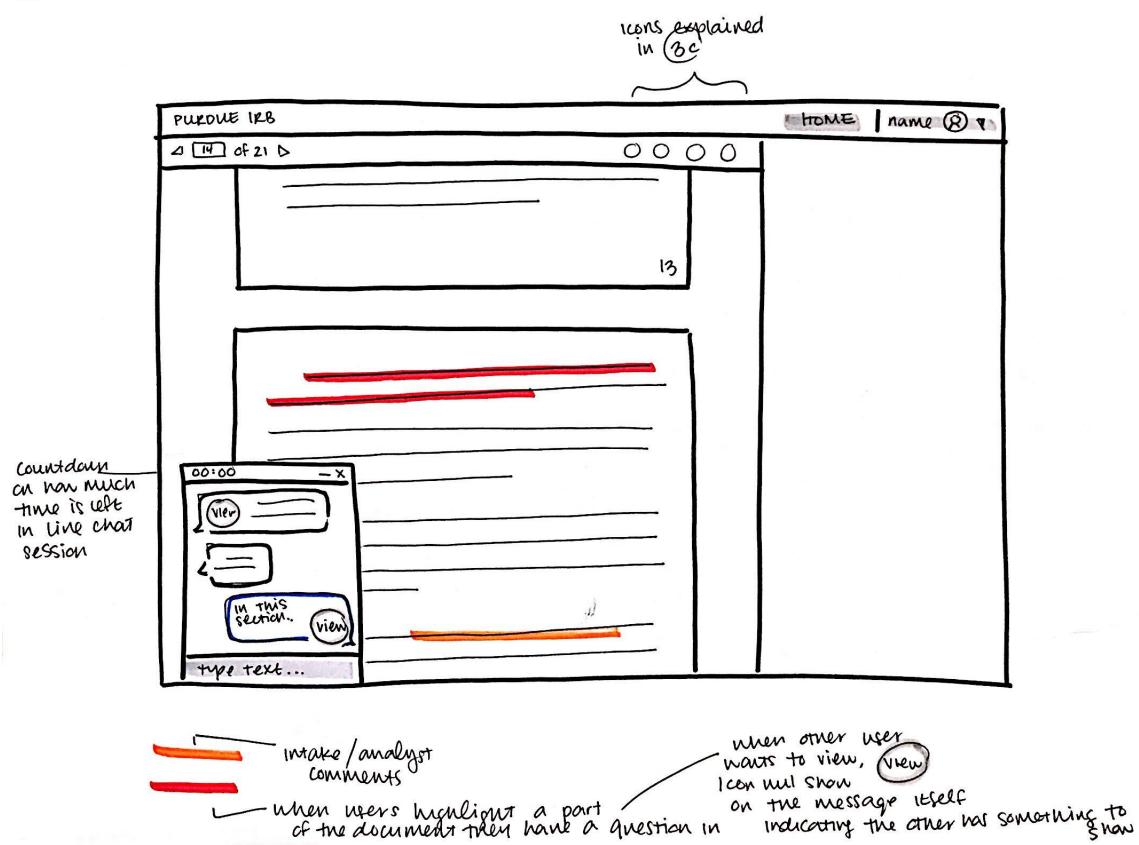
# Ideation

## INITIAL SKETCHES

### (3)c PROTOCOL HOME - comments



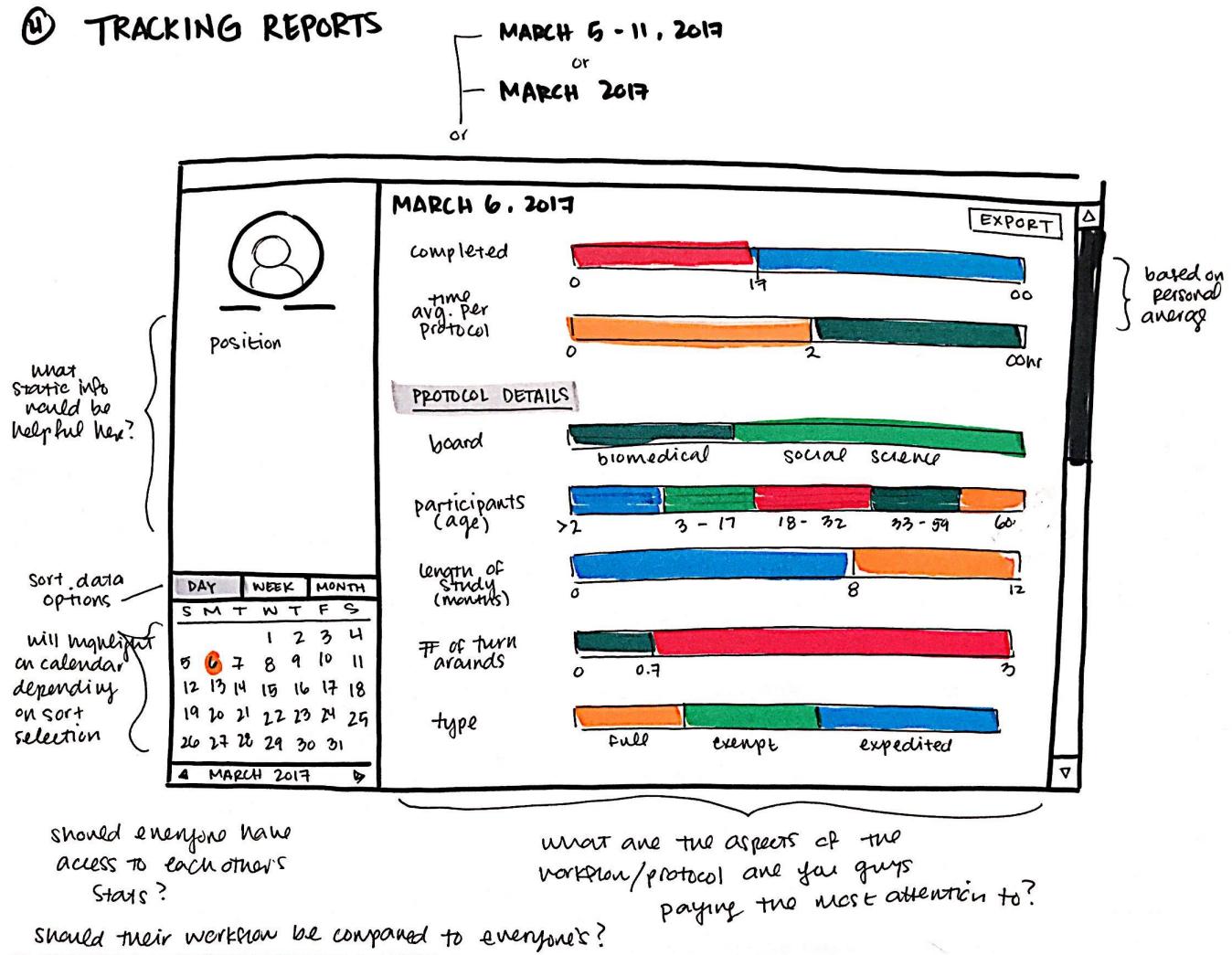
### (3)d PROTOCOL HOME - line chat



# Ideation

## INITIAL SKETCHES

### ① TRACKING REPORTS



# Feedback

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## FEEDBACK

Upon completion of these initial sketches, the concept of this application and its function within the organization were proposed to the users. From this meeting and the review of these wireframes, it became readily apparent that the IRB needs lie far closer to short term solutions to these goals- as developing a software application as described by the wireframes is expensive in both time and monetary concerns.

On specific features, users were interested in such a tool, one which would be an easy-to-use middle ground for their document handling. However, some specific features seemed of lesser or negative impact. One such was the scheduled chat feature, which was wireframed to address the need for contact between PI and inclusion of this contact with the protocol. This brought up many questions and concerns regarding the nature of this chat, and ultimately users felt that more work can be accomplished via a phone call or in person meeting.

From here, an additional focus on collecting more secondary research became apparent. In lieu of a complete software overhaul, for which there is little budget and large institutional resistance, proper action would be a companion tool which the IRB may use in tandem with the current workflow to handle things such as the tracking of data and secure storage of protocol information. Such a tool would be useful for office management, reducing the time it takes to do tasks such as assigning analysts to protocols or searching through protocols given a certain criteria.

# Recommendations

scrumwise application

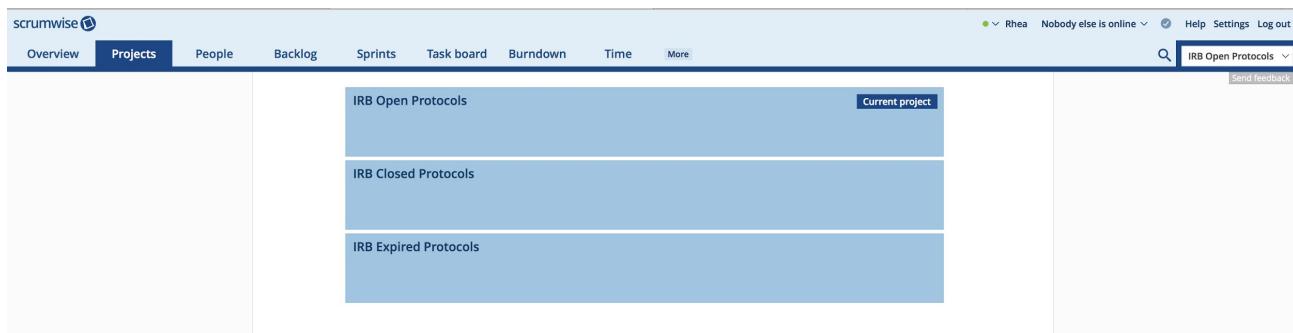
# Recommendation

## SCRUMWISE OVERVIEW

Scrumwise is a project management tool created to streamline collaboration within teams. It has a wide variety of features, including project/task visualization, activity tracking, team communication, time tracking, and graphing progress. Using this tool can help provide insights into a workflow.

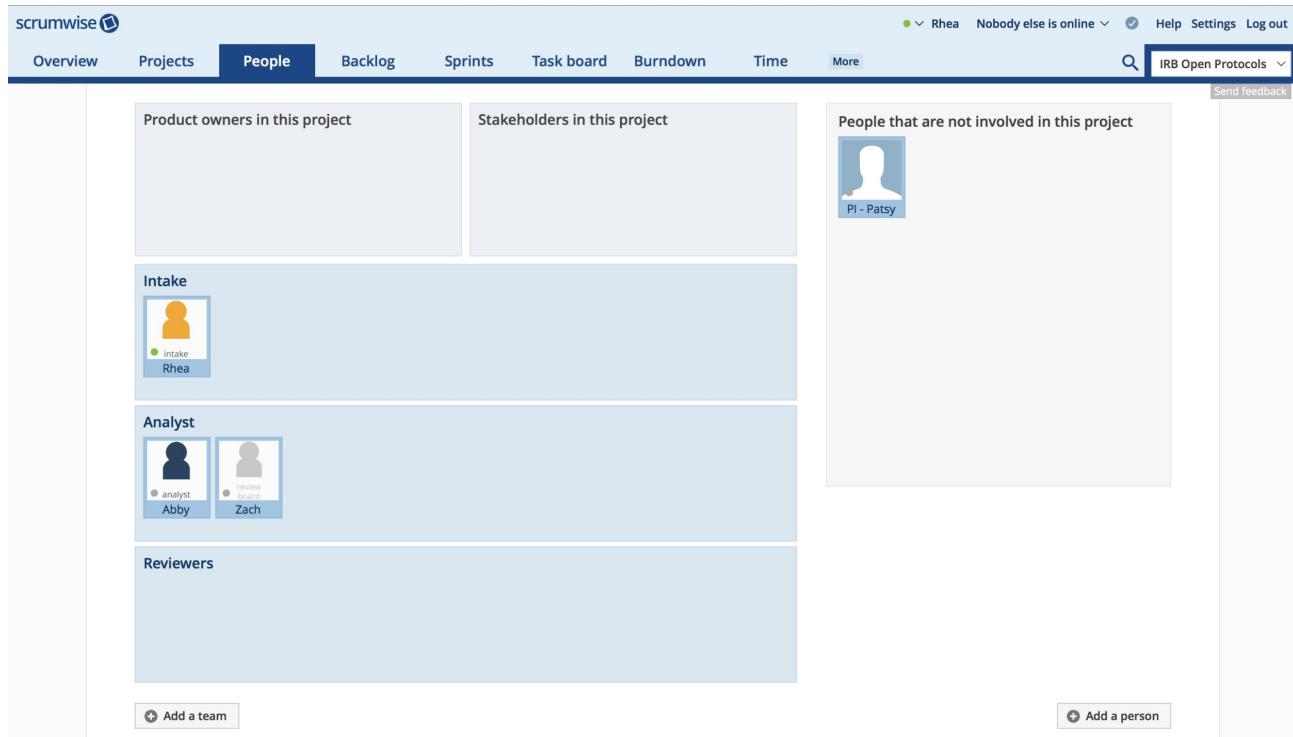
Scrumwise ideally can be used as a companion tool with Coeus. Its primary value to IRB lies in the ability to track changes.

First-time setup would involve creating projects to sort protocols under the Projects tab.



The screenshot shows the Scrumwise interface with the 'Projects' tab selected. The main content area displays three categories of protocols: 'IRB Open Protocols' (which is the 'Current project'), 'IRB Closed Protocols', and 'IRB Expired Protocols'. The top navigation bar includes links for Overview, Projects, People, Backlog, Sprints, Task board, Burndown, Time, More, Help, Settings, and Log out. A search bar and a dropdown menu for 'IRB Open Protocols' are also visible.

Next, in the People tab teams can be created, and IRB staff can be added to the project and sorted into the teams. An optional step is to add PIs to the side section in order to use the chat functionality.



The screenshot shows the Scrumwise interface with the 'People' tab selected. The left sidebar lists teams: 'Intake' (with Rhea), 'Analyst' (with Abby and Zach), and 'Reviewers'. The main content area shows sections for 'Product owners in this project' (empty), 'Stakeholders in this project' (empty), and 'People that are not involved in this project' (Pi - Patsy). At the bottom, there are buttons for 'Add a team' and 'Add a person'. The top navigation bar is identical to the previous screenshot.

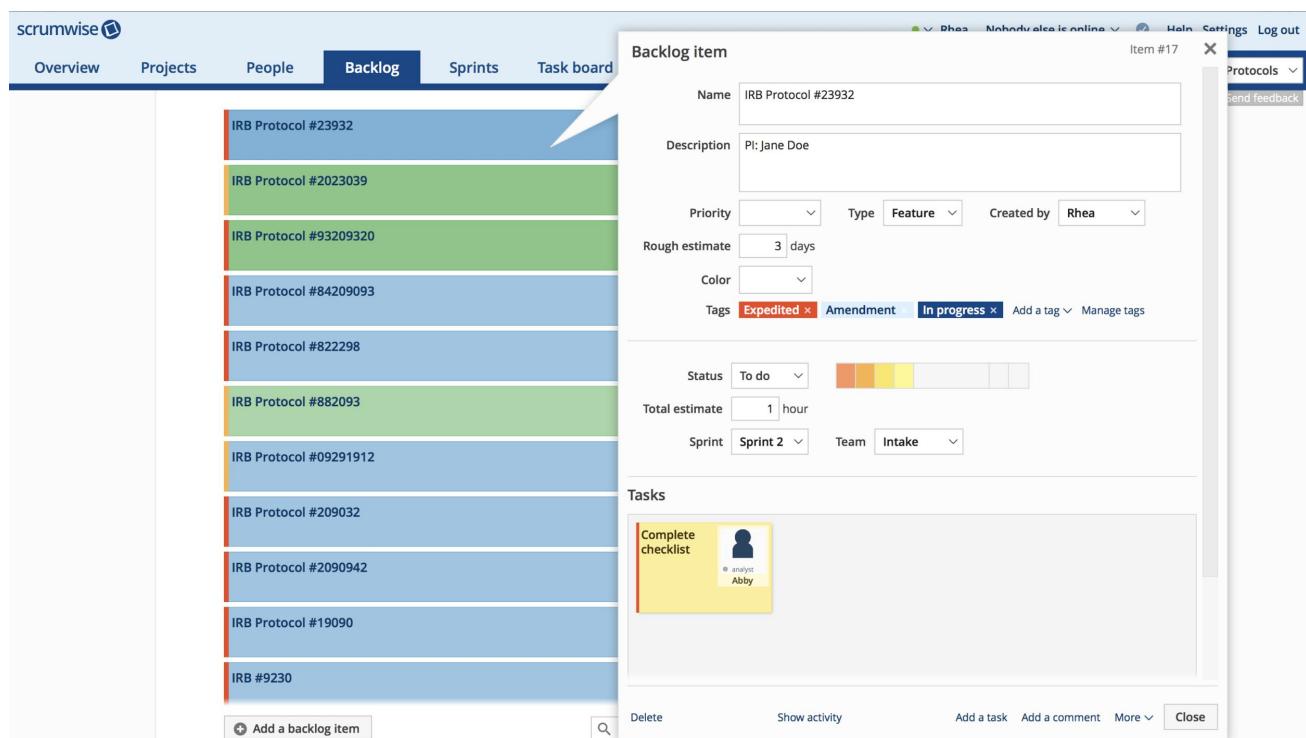
# Recommendation

## SCRUMWISE FEATURES

Protocols will be listed under the Backlog tab. Each protocol item has identifying characteristics - the name (protocol ID), description (principal investigator), and tags such as Expedited and Amendment (which can be searched through). Additionally, protocols can be assigned to teams; individual tasks can be added and assigned to people.



The screenshot shows the Scrumwise Backlog view. At the top, there's a navigation bar with links for Overview, Projects, People, Backlog (which is highlighted in blue), Sprints, Task board, Burndown, Time, More, Help, Settings, and Log out. A search bar and a dropdown for 'IRB Open Protocols' are also present. Below the navigation is a table listing ten IRB protocols. Each row contains the protocol ID, estimated time, current status, and a color-coded progress bar. The columns include Name, Duration, Status, and Tags. The first protocol, IRB Protocol #23932, is marked as 'Expedited' and 'Amendment'. The second protocol, IRB Protocol #2023039, is marked as 'Full Review' and 'New'. The third protocol, IRB Protocol #93209320, is also marked as 'Expedited' and 'New'. The fourth protocol, IRB Protocol #84209093, is marked as 'Expedited'. The fifth protocol, IRB Protocol #822298, is marked as 'Expedited' and 'Amendment'. The sixth protocol, IRB Protocol #882093, is marked as 'Full Review' and 'Revision'. The seventh protocol, IRB Protocol #09291912, is marked as 'Full Review', 'New', and 'Revisions - PI'. The eighth protocol, IRB Protocol #209032, is marked as 'Expedited' and 'Revision'. The ninth protocol, IRB Protocol #2090942, is marked as 'Expedited' and 'Revision'. The tenth protocol, IRB Protocol #19090, is marked as 'Expedited' and 'Renewal'. The bottom of the table has buttons for 'Add a backlog item' and a search bar. To the right, there are 'Show' and 'All items' dropdowns.

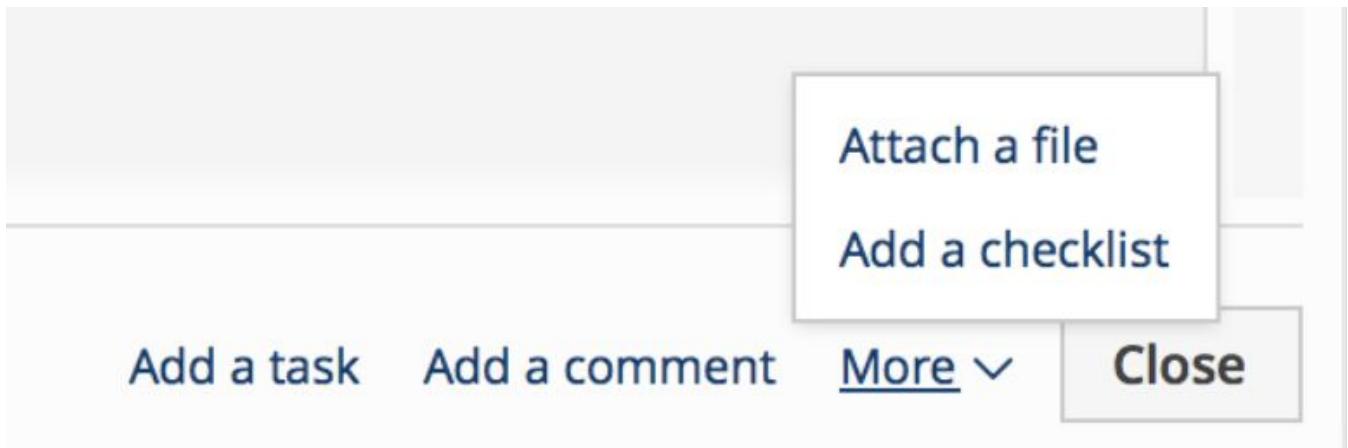


This screenshot shows a detailed view of an IRB protocol from the backlog. On the left, the same list of ten IRB protocols is visible. On the right, a modal window titled 'Backlog item' is open for 'IRB Protocol #23932'. The modal contains fields for Name (IRB Protocol #23932), Description (PI: Jane Doe), Priority (dropdown), Type (Feature), Created by (Rhea), Rough estimate (3 days), Color (dropdown), and Tags (Expedited, Amendment, In progress). It also includes sections for Status (To do), Total estimate (1 hour), Sprint (Sprint 2), Team (Intake), and Tasks. A task card for 'Complete checklist' is shown, assigned to a user named Abby. At the bottom of the modal are buttons for Delete, Show activity, Add a task, Add a comment, More, and Close.

# Recommendation

## SCRUMWISE FEATURES

In addition to assigning tasks, the files can be attached from Coeus. This is beneficial because every change made is logged in Scrumwise with details of when the change was made, what changed, and who made the change.



This screenshot provides a detailed view of the activity history for a specific backlog item in Scrumwise. The activity log is titled 'Backlog item' and lists the following events:

- You started Sprint 2. Last Thursday at 6:30 PM
- You assigned this backlog item to the team "Intake" in Sprint 2. Last Thursday at 6:28 PM
- You marked this backlog item as ready for sprint. Last Thursday at 6:28 PM
- You changed the estimate in this backlog item to 1 hour. Last Thursday at 6:28 PM
- You changed the task estimation options in this backlog item. Last Thursday at 6:28 PM
- You marked this backlog item as ready for estimation. Last Thursday at 6:28 PM
- You changed the rough estimate in this backlog item to 3 days. Last Thursday at 6:27 PM
- You assigned the task "Complete checklist" in this backlog item to Abby. Last Thursday at 6:16 PM
- You added the task "Complete checklist" in this backlog item. Last Thursday at 6:16 PM
- You added the checklist item "Check" in the checklist "Check" in this backlog item. Last Thursday at 6:16 PM

At the bottom of the activity log, there are buttons for 'Delete', 'Hide activity', 'Add a task', 'Add a comment', 'More ▾', and 'Close'. The 'More ▾' button is highlighted in blue. The bottom of the screen also features a footer with a search bar, a 'Show All items ▾' button, and a page number '32'.

# Recommendation

## SCRUMWISE FEATURES

The sprint view allows for time estimation and allocation, assignment to individuals, and an overview into what is being currently worked on.

The screenshot shows the Scrumwise application interface. At the top, there's a navigation bar with links for Overview, Projects, People, Backlog, Sprints (which is the active tab), Task board, Burndown, Time, More, Help, Settings, and Log out. A search bar is also present. Below the navigation is a main content area divided into several sections:

- April Sprint:** Shows progress for Analyst (1 hour completed) and Reviewers (2 hours completed). A button to "Resume this sprint" is visible.
- Sprint 2:** Shows Intake (33 hours ahead), Analyst (38 hours ahead), and Reviewers (40 hours ahead). Buttons for "Complete this sprint" and "In progress" are shown.
- Backlog items that are not assigned to any sprint:** A list of backlog items with their status (Expedited, Revision, New).
- Bottom controls:** Buttons for "Add a sprint", "Show All sprints", a search bar, and "Add a backlog item".

Protocols can also be easily searched through, using keywords such as IDs, tags, and assignments.

The screenshot shows two search results windows from the Scrumwise application:

- Search results for 'expedited':** Shows a list of backlog items and tasks labeled as expedited. Examples include PI #9844, IRB #83209, and IRB Protocol #23932.
- Search results for 'zach':** Shows a list of backlog items and tasks assigned to the user 'Zach'. Examples include PI #9844, IRB #83209, and IRB Protocol #84392.

# Recommendation

## SCRUMWISE FEATURES

Under the task board, different protocols and their individual tasks are visualized along with who they are assigned to. Protocols can be moved around to track progress. These columns can be renamed to reflect different statuses for the protocol.

Additionally, at the bottom there is a filter, which allows users to easily see what they are currently working on.

The screenshot shows the Scrumwise Task Board interface. At the top, there is a navigation bar with links for Overview, Projects, People, Backlog, Sprints, Task board (which is highlighted in blue), Burndown, Time, and More. On the right side of the header, there are user status indicators (Rhea, Nobody else is online), Help, Settings, and Log out options. A search bar labeled "IRB Open Protocols" is also present.

The main area is the Task Board, divided into four columns: Backlog item, To do, In progress, and Done. Each column contains several cards representing different protocols. Each card includes the protocol number, its status (e.g., Expedited, In progress, Needs Review), the assignee (e.g., Rhea, Abby, Zach), and the time spent (e.g., 4 hours, 2 hours, 1 hour). The "In progress" and "Done" columns also show progress percentages (e.g., 0%, 100%).

At the bottom of the board, there are buttons for "Sprint status" (set to "In progress"), "Complete this sprint", and a search bar. On the far right, there is a sidebar with filtering options: "Edit this board", "Sprint" (set to "Sprint 2"), "Show" (set to "All teams"), and a dropdown menu for "All teams" which lists "You", "Your team", "All teams", "Intake", "Analyst", "Reviewers", "Abby", "PI - Patsy", "Rhea", and "Zach".

# Trends

- Coeus Lite slows down the review process
- multi-platform slows down the review process
- a lot of time is spent on missing PI documents
- no tracking systems
- communication is very important

# Recommendations

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There are many other tools out there that are similar to Scrumwise. The following list shows the trends that we found through all our research this semester. Whether it would be a new tool or use an already existing, take the following as guidelines for features that it should have in order to have a more efficient workflow. Here are the trends we found:

- Coeus Lite slows down the review process
- Multi platform slows down the review process
- A lot of time is spent on missing PI documents
- No tracking systems
- Communication (between PI, intake, and analysts) are very important

Each trend will be accompanied by a direct quote from our interviews, some rationale, and some suggestions for the future tool.

## COEUS LITE SLOWS DOWN THE REVIEW PROCESS

"[The review process] **takes longer now**, there's **no support** for Coeus."

There is currently no support for Coeus Lite. This means that any changes wanted on the tool can't be made. It is extremely difficult to work on a tool like this because they have to constantly be updated. For the future tool, make sure that there are trustworthy developers constantly working on it. This will make it easier for the IRB department to make sure that bugs are fixed.

## MULTI PLATFORM SLOWS DOWN THE REVIEW PROCESS

"We make sure that before we give it to a chair, that all the documents that **need to be in PDF format** are **properly labeled** and **changed**."

As we were going through the interviews and observations, multiple different platforms kept coming up that are being used by different users. Some like to take physical notes, some keep it on an e-mail draft, and so on. Switching over to a new tool that would have all the trends covered would solve this problem because it would result in getting rid of paper protocols. The following list are all the different platforms we uncovered that are used by the entire review board.

- Coeus Lite
- Physical notepad
- Microsoft Word
- Mail draft
- Printed checklist
- Electronic protocol
- Printed protocol

# Recommendations

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## A LOT OF TIME IS SPENT ON MISSING PI DOCUMENTS

"PIs are **supposed** to attach all documents, **but don't know how** to do it... each protocol has at least one thing that requires **rejection or a call.**"

Intakes and analysts spend a decent amount of their valuable time communicating with the Principle Investigators because there's something wrong with the document. The protocol is sent back to the PI's **at least** once throughout the process. Downloading PDF files and having PI's manually fill it out and re-upload gives a lot of opportunities for error. There is no way for them to be notified if they missed a question. Having an online form system would not only ensure that PI's send all that they need, but also help the answers be more consistent.

## NO TRACKING SYSTEMS

"Coeus has no reporting capabilities, so **nobody knows** what's routed to me on what day at what time."

Having a tracking system would be beneficial in numerous ways for the IRB. It will uncover time on task and that could potentially help prioritize what needs to be focused on when changing the workflow. This will also keep a record on where the file is and who has worked on it, eliminating the lost protocols as well.

## COMMUNICATION IS VERY IMPORTANT

"**40%** of [their] decisions are bounced off of other analysts."

There must be an easier way to share protocols between analysts that wouldn't require physically getting up with a stack of paper or needing to look up the protocol number. If there was a capability of the new tool to immediately share, it would save a lot of time.

# Summary

# Summary

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## WHERE WE ENDED

We finished a lot of user interviews with the Purdue IRB Review Board to understand their wants and needs and started to look into other possible tools to look into. No development or coding was done. We have one suggested tool and low-fidelity wireframes if they were to develop their own tool.

## NEXT STEPS

We suggest for the IRB to look into developing their personalized tool to fit all their needs, or to find an existing tool that has the features stated on pages 36-37.