Sliquidhub Clinical Consent Management

Elizabeth Kaufer | June 1, 2017



EXECUTIVE SUMMARY

Time savings does not out weigh additional feature needs

LiquidHub tested a prototype of Clinical Consent with 12 users. Participants responded well to the prototype's usability, consent form workflow, and the concept of customizing it to a specific institution. They thought it had potential to make it easier to create consent forms and save time.

Additional functionality, such as generating other IRB documents, editing and version control, would add further value to individual researchers and institution overall.





AGENDA

Project Team
 Project Goals & Objectives
 Method
 Findings and Recommendations
 Conclusions and Next Steps
 Appendix

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Project Team

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PROJECT TEAM

Clinical Consent Project Team

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Project Goals & Objectives

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PROJECT GOALS & OBJECTIVES

Assess researcher reactions to Clinical Consent prototype

Evaluate the Clinical Consent concept:

• Gauge reactions to the Clinical Consent prototype and its potential use at institutions.

Evaluate Clinical Consent usability:

- Evaluate the new consent-form workflow.
- Determine the functionality Clinical Consent should include.





section 3 Method

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METHOD

Usability & Concept Testing

LiquidHub tested the client's prototype consent-management desktop application with nine participants in Philadelphia and three remote participants, March 30 – April 4, 2017.

Participants included researchers involved in the design of participant consent forms from academic institutions, hospitals and private practices. (see Appendix for details).

During the 1-hour sessions, participants explored the prototype and walked through the consent form-creation workflow.

Consent Form Required Fields
Which of the following points are relevant with respect to patie Follow the instructions of the Protocol Director and study staff. Take the study drug as instructed (if device, explain what is required for study com Tell the Protocol Director or research staff if you believe you might be pregnant or Keep the study drug in a safe place, away from children and for your use only. Keep your diaries as instructed. Complete your questionnaires as instructed. Ask questions as you think of them. Tell the Protocol Director or research staff if you change your mind about staying in
Go Back Save Progress



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Findings & Recommendations

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Findings & Recommendations

Usability

Future Iterations

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"I think there's a need, I think [Clinical Consent] does solve a few problems that cause people issues. I like the notion of it providing a universal standard place that has everything that's appropriate to the individual studies."

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Prototype was easy to use overall

Participants found the site user-friendly and well-organized.

• They said the new study workflow made sense, and felt confident that it would include everything they needed on the form.

After understanding the high degree of customization available, most participants were very interested in using it.

(1) However, several participants didn't notice the hamburger menu and could not return to the dashboard.

 Not all users were familiar with the hamburger menu or did not expect to see it on a desktop application.

Recommendations:

 Replace the hamburger menu with a "Menu" button.



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View

Last Updated: 3/2/2

Last Updated: 2/27/

View

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Last Updated: 2/14/;

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Riquidhub 13

Selecting the right forms requires more context

Participants understood the purpose of the Form Categories pop-up.

- They would expect to see other protected populations or other institutions they work with as additional categories.
- Two participants wanted to know ahead of time what forms would be included in a category.

Generally, the title of the form was sufficient for the participant to pick what form they needed.

- To make sure they picked the correct forms, participants wanted a brief description of the form and the types of studies it could be used for, as well as a last modified date or version number.
- Five participants wanted the forms to be grouped together to make the page easier to scan.

Recommendations:

- Combine Form Categories and Select Applicable Form pages.
- Organize form templates by population or institution category, e.g., General Hospital or University of Pennsylvania.
- Include the types of studies the form could be used for (e.g., qualitative survey).
- Include a version number.

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RECOMMENDED CONCEPT

ategorize form mplates

rs do not want to waste time trying to the forms they need. Grouping forms by gory will save user time and effort.

orms have generic or similar titles, users not know which ones to pick. Categories brief descriptions will also ensure that rs select the correct forms for their study.

bending on the institution's preference, egorize the form templates by population e or institution (for instance, if they have earch partners with their own IRBs). This allow users to more quickly find the right ns they need for their research.

Allow users to collapse categories to the it easier to scroll.



Workflow does not indicate what's ahead

Participants understood the wizard-style workflow and did not have strong preference for a particular form style.

Based on the workflow, some participants were unsure form would cover all the necessary sections of the consent form.

• The workflow does not indicate what sections are coming up, which creates uncertainty in the user.

Five participants create forms over several days or prepare different sections out of order.

• They mentioned it might be tedious to have to click through multiple pages to get to the section they wanted.

Recommendations:

• Add section tabs to the workflow that allow user to skip to different sections of the form.

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Progress			bi
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RECOMMENDED CONCEPT

se tabbed sections to reak up workflow

ers want to understand what they need to before starting a project. Tabbed tions will let the user see what ormation they will need to provide on form and let them skip to different tions.

by users to save or advance without ng out mandatory fields to facilitate rking on a form out of order and over ltiple sessions.

ers who return to a form after several rs may forget to fill out certain sections. Inde a warning before generating the al PDF if any required fields are missing.



Guidance needs differ by expertise level

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Participants wanted on-page instructions helping them follow IRB guidelines.

Four participants said that needing to click a tooltip to see each section's instructions would be annoying.

Two said they wouldn't need on-page instructions because they were very familiar with the form.

Recommendations:

- Include instructions on each page.
- Allow users to toggle instructions on or off.

Clinical Consent Consent Form Required Fields Progress 0% Complete Study Name: Brief Description 0/350 Patient Benefits 0/350 Purpose of research: "[Instructions] have to be in here or it's not useful."







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RECOMMENDED CONCEPT



Allow users to toggle instructions on/off

Toggling instructions "on" would show instructions underneath each section header based on the institution's IRB guidelines.

(1) Toggling instructions "off" would hide instructions from view.

This will give experienced users a more streamlined experience while allowing them to quickly refer to the guidelines if needed.

Accommodating users of varying expertise levels will add more flexibility and value to the application.

Users need to confirm the right disclosures are in the consent form

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Participants wanted use previews to make sure that the right text was going to be included in their consent form.

• (1) Most participants guessed that they could see that text by clicking on the tooltip.

Participants also wanted to preview the form before generating it as a PDF (see page 28).

Recommendations:

• Include full-text previews in tooltips.

Clinical Consent
Consent Form Required Fin
Select criteria for project
 Personal Health Information will be disclosed Specimens will be collected Samples will be sent out of institutions Samples will not be saved Samples will not be saved Women of Chilbearing Potential Genetic testing (current study or future resear Gene transfer MRI
Go Back Save Progress



Additional details on consented patients help users manage studies

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Participants considered keeping track of consented patients and recruitment goals helpful.

Participants wanted additional fields, like recruitment site, treatment group, or specific patient attributes, or the ability to customize what fields are available.

• Six mentioned that this could be a useful tool to analyze the success of the consenting process, for instance by comparing different recruiting sites.

Recommendations:

- Allow users to customize tracked information for consented patients.
- Add analytic tools or an export feature to facilitate deeper analysis.

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400	Malaria Liberty					17 TUN 2016
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_		Prev Page	1, 2, 3, 4	Next Page		

Access to consent forms must be controlled

Participants liked the idea of being able to add other team members and collaborators to a study.

Anyone related to the study would need access to the consent forms, however, participants wanted to control who would be able to view and edit the forms.

Recommendations:

• Include functionality for principal investigators to control who can view, comment, edit or delete forms.

Clinical Consent

Reducing Sleep Disparities in Minority Children









Findings & Recommendations

Usability

Future Iterations

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FUTURE ITERATIONS

Study management is a huge asset

Participants said a centralized study-document repository would help them find items better than their current file-organization methods.

- They would access other studies at their institution to see prior activity and to find other IRB-approved documents on which to base their own applications.
- Categorizing or tagging studies based on population type, study type or principal investigator would help users find them more easily.
- Some participants only wanted to see their own studies on their dashboard, since there would be too much content on otherwise.

Participants wanted to see study statuses (e.g., collecting data, pending approval).

Recommendations:

- Build out document management capabilities, including tagging, tracking and document storage.
- Include a field for the status of a study.

Clinical Consent

23 Total Studies

Reducing Sleep Disparities in Minority Children

Infant Sleep Hygiene Counseling Trial

Physiologic Effects of Sleep Restriction

Sleep Self-Regulation Using Mental Imagery

Long term effects of OTC Sleep Medication



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"Compared to the way I've [created consent forms] in the past, this makes it easier. ...I don't have to go hunting around or looking in different places [for forms or previous studies]. There's a centralized repository."

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GUIDES AND GRID

Research departments would value institutional-level management

Four participants stated that seeing all the studies going on in the department would help them manage resources and understand the scope of research going on in their institution.

Four participants expressed interest in IRB reviewers reviewing drafted forms directly within the program to save time and help them track the application process.

 Creating documents through the Clinical Consent's templates would also speed up IRB review time by using standardized language.

Recommendations:

- Promote the value of Clinical Consent to help institutions manage research departments.
- Develop an IRB view of the application, which includes review/comment/approval functionality.

Clinical Consent

23 Total Studies

Reducing Sleep Disparities in Minority Children

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Infant Sleep Hygiene Counseling Trial

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Physiologic Effects of Sleep Restriction

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Sleep Self-Regulation Using Mental Imagery

Long term effects of OTC Sleep Medication

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FUTURE ITERATIONS

Users need support throughout the whole IRB process

Clinical Consent is missing functionality. Participants wanted to generate all documents for an IRB application, not just consent forms.

• If it only handles consent forms, it's just another place users need to go to find documents and does not save enough time or effort.

Preparing documents to IRB standards, waiting for approval, and changing documents take up a lot of time, especially if researchers must submit to multiple IRBs.

• Documents must adhere to specific standards from each IRB, which are tedious to manage and follow.

One participant mentioned that saving documents, such as signed consent forms, within the program would also help facilitate IRB audits.

Recommendations:

- Expand Clinical Consent to include all IRB application documents.
- Include IRB tracking as part of an individual study's status (e.g., "Submitted to IRB on April 12, 2017").
- Build out document management capabilities (see page 24).

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	Reducing S	leep Disp
		Consent Form
		12

"This is a great start, but the real pain points with some of these studies aren't [consent forms], it's all the other stuff that goes to IRB."

parities in Minority Children





"The more comprehensive a tool [Clinical Consent] can be, the better."



FUTURE ITERATIONS

Users need to edit and track forms

Participants wanted to view an editable version of the form before generating final PDF.

Many participants also wanted to be able to track changes by user, especially if requested by IRB.

• Tracking facilitates IRB auditing and enables more successful multi-user collaboration.

Depending on the type of study, some participants need additional flexibility from their consent forms, for example, rearranging sections of a form.

Recommendations:

- Include editing and tracking functionality.
- Allow the user to preview an editable version of the generated consent form before finalizing as a PDF.

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100% Complete
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Informed Consent for Qualitative Studies (Short Form Consent)



FUTURE ITERATIONS

Finalized forms need to be easy to find

Tracking consent-form versions is important to participants, especially after IRB approval.

Half of all participants mentioned that trying to find final versions of study documents was difficult in their current file-organization systems.

- Documents in shared drives can also be deleted or moved accidentally.
- File names are often inconsistent.

Some participants create multiple versions of a form for a single study, for example, if the study has multiple legs or requires translated documents.

Recommendations:

- Separate draft and final forms within a study.
- Lock forms from further editing after IRB approval.
- Automatically generate version numbers for finalized forms.
- Allow users to duplicate forms within a study to create new versions.

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Conclusions & Next Steps

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CONCLUSION

Clinical Consent is easy-to-use but needs more functionality

Participants thought the prototype was intuitive and could make their work more efficient.

The consent form workflow was easy to understand and consolidating all their studies in one place would help mitigate file organization issues within their institutions.

However, participants wanted the program to generate more than just consent forms and allow them greater flexibility to edit forms.



Build out additional capabilities and conduct further testing

Consolidate the consent form workflow to further streamline new consent form generation.

Develop document management and editing capabilities.

Conduct testing on an updated, low-fidelity prototype with additional users.

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Appendix

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APPENDIX

Participant Summary

Participant #	Title	Workplaces	Responsit
P01	Research Director/Coordinator	Hospital	My team l
P02	Psychiatrist	Research institutes	l was resp
P03	Psychiatrist	Private practice and hospital	l alone wa
P04	Research Director/Coordinator	Research institute	l was resp
P05	Associate Professor	Academic institution	l was resp
P06	Assistant Professor	Private practice and academic hospital	l alone wa
P07	Scientist	Research institute	My team
P08	Research Director	Research institute	Someone
P09	Clinical Research Project Manager	Hospital	l was resp
P10	Associate Professor	Academic institution	l was resp
P11	Senior Scientist	Academic institutions	Team mos
P12	Physician	Academic institution and hospital	l alone wa

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- as responsible

