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William J. Hughes Technical Center
Aviation Research Division
Atlantic City International Airport
New Jersey 08405

Electronic Institutional Review Board (eIRB) Usability Evaluation

November 2025

Final report

U.S. Department of Transportation
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16. Abstract

The process of submitting an application for research involving human participants to the Institutional Review Board (IRB) at the Federal Aviation Administration (FAA) William J. Hughes Technical Center for Advanced Aerospace needs modernization. We conducted an evaluation of the first iteration of a newly proposed electronic Institutional Review Board (eIRB) system to assess its usability, provide insights and recommendations for improvements, and guide the eIRB system's development to improve user experience. We used nine federal employees from the Technical Center, the Department of Transportation (DOT) at the Volpe Center, and Civil Aerospace Medical Institute (CAMI).

We evaluated three pages within the system: the Registration page, the IRB Submission Form Fill page, and the Submit Protocol for IRB Review page. We also guided participants through four tasks: registering a protocol with the local Technical Center IRB, completing an IRB submission form, submitting a protocol, and submitting a protocol revision. Participants also completed the System Usability Scale (SUS) and answered additional survey questions pertaining to their experience using the eIRB system. We found that the overall eIRB system had above average usability although there are elements that need improvement. Several considerations must be made in the design and implementation of the eIRB system, especially considering the importance of remaining in compliance with federal regulations regarding the protection of participant Personally Identifiable Information (PII) and data management. The design of a system that allows users to easily and efficiently accomplish their goals is only half the battle; enforcement of compliance with the Common Rule and FAA Order 9500.25C for those engaging in research or test and evaluation activities involving human subjects must occur in order for eIRB system to serve its true purpose.

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Acronyms

Acronym	Definition
CAMI	Civil Aerospace Medical Institute
DOT	Department of Transportation
eIRB	Electronic Institutional Review Board
FAA	Federal Aviation Administration
HFDS	Human Factors Design Standard
HSI	Human-Systems Integration
IRB	Institutional Review Board
PI	Principal Investigator
PII	Personally Identifiable Information
PIV	Personal Identification Verification
SUS	System Usability Scale
UX	User Experience

Executive summary

Institutional Review Boards (IRBs) analyze studies to ensure that they comply with ethical standards and regulations as well as adequately protect participants from research-related risks. The Federal Aviation Administration (FAA) William J. Hughes Technical Center for Advanced Aerospace has run a local IRB since 1998. The current process for submitting an application to the local IRB at the Technical Center is in need of modernization, as the process has remained the same since the Technical Center began reviewing IRB submissions in 1998. The Human-Systems Integration (HSI) branch (ANG-E5B) conducted an expert usability evaluation of a newly proposed electronic Institutional Review Board (eIRB) system. The purpose of this evaluation was to evaluate the overall usability of the system's first iteration and provide insights that will inform design recommendations for improvements and guide the next phase of the eIRB system's development.

We evaluated the usability of three pages within the eIRB system: the Registration page, the IRB Submission Form Fill page, and the Submit Protocol for IRB review page, with nine federal employees from the Technical Center, the Department of Transportation (DOT) Volpe Center, and Civil Aerospace Medical Institute (CAMI). We also guided participants through four tasks that a typical user would complete using the eIRB system: registering a protocol with the local Technical Center IRB on the Registration page, completing an application on the IRB Submission Form Fill page, submitting a protocol on the Submit Protocol for IRB Review page, and submitting a protocol revision.

Participant comments were organized according to navigation, functionality, design aesthetic, instruction and wording, and user experience. Comments were further sorted by things that participants liked about the system, desired changes, and any confusions or questions. We found that the overall eIRB system had above average usability upon administration of the System Usability Scale (SUS) to all participants. Participant comments matched this finding, although there are elements of the eIRB system that were found to need improvement. It is possible that a more extensive study with a more diverse participant pool would highlight usability issues that were not uncovered by this current study. The next step will be to repeat this study, having implemented some of the most pressing usability improvements, with a greater variety of participants, particularly more test and evaluation personnel in addition to researchers, who would benefit from the use of this system.

1 Introduction

Institutional Review Boards (IRBs) analyze studies to ensure that they comply with ethical standards and regulations as well as adequately protect participants from research-related risks (Office for Human Research Protections, 2021). The Federal Aviation Administration (FAA) William J. Hughes Technical Center for Advanced Aerospace has run a local IRB since 1998. Researchers at the Technical Center seeking to conduct research involving human participants are required to submit an application to the local Technical Center Institutional Review Board (IRB). This application is reviewed by the local IRB chair at the Technical Center. The current process for submitting an application, which was established in 1998 when the Technical Center began reviewing IRB submissions, consists of a significant amount of correspondence between the Principal Investigator (PI) and local IRB chair. Currently, researchers are required to submit their IRB application forms as well as other documentation relevant to the study (such as questionnaires, test plans, or informed consent paperwork) to the local Technical Center IRB chair via email or fax. From there, correspondence between the local Technical Center IRB chair and the PI pertaining to the submitted documents would occur via email, telephone, or in person. This process has introduced inefficiencies and delays in moving forward with research or test and evaluation activities. Additionally, the current process has contributed to the disorganization of important documentation relevant to research and test and evaluation protocols as well as inadequate protection of human participants.

While the practice of submitting a research application remains a critical component of ethical research oversight, it is evident that the existing process requires improvement and modernization. In 2024, the local IRB at the Technical Center launched an effort to develop a more efficient system to enhance communication and coordination between researchers and evaluators as well as to ensure the protection of participants' Personally Identifiable Information (PII). To address this, researchers at the Technical Center initiated the development of a system that would allow researchers to submit their protocol application through an electronic Institutional Review Board (eIRB). Following informal prototyping reviewed by a small group within the Technical Center, the team ultimately selected Microsoft Power Apps as the platform to host the system.

Research is needed to assess how users interact with the eIRB system and to evaluate the overall usability of the system's first iteration. In this study, we seek to provide insights that will inform design recommendations for improvements and guide the next phase of the eIRB system's development with the goal of improving user experience.

1.1 Background

Submitting protocols for review at the Technical Center began in 1998. At this time, continuing through to the present day, the process for protocol submission involved extensive email exchanges, phone calls, and faxing documents back and forth between the PI and the local Technical Center IRB chair. This approach has introduced inefficiencies and increased the potential for miscommunication, lost documentation, and non-compliance with research regulations and requirements.

The protection of human research subjects has its roots in The Belmont Report, created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and published by the Department of Health and Human Services (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The Belmont Report summarized ethical guidelines for human subject research and focuses on three core principles: Respect for Persons, Beneficence, and Justice. These principles have been applied in the development of informed consent guidelines, assessment of risk and benefits for subjects, and the selection of human subjects in research endeavors. The Belmont Report was developed following the signing of the National Research Act after ethical issues arose during the Tuskegee Syphilis Study. The National Research Act issued Title 45 CFR part 46 subpart A (45 C.F.R. § 46), also known as the Common Rule, a Federal Regulation that outlines requirements for the protection of human participants published by the Department of Health and Human Services and amended in 2018 (Protection of Human Subjects, 2018). In alignment with these standards, the Department of Transportation adopted its own regulation, Title 49 CFR part 11 (49 C.F.R. § 11), which reflected the Common Rule and ensured consistency in the ethical oversight of research conducted or supported by DOT agencies (Protection of Human Subjects, 2018). In October 1996, FAA Order 9500.25 was created with the purpose of establishing standardized policies and procedures for conducting research involving human subjects, promulgating the model Federal policy for protection of human subjects in research sponsored or conducted by the FAA, and establishing the FAA IRB. Since its original development, FAA Order 9500.25 has undergone several revisions, with the most recent being FAA Order 9500.25C in February 2022 (Federal Aviation Administration, 2022). As defined by FAA Order 9500.25C, research refers to “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (Federal Aviation Administration, 2022). This definition of research was applied to the development of the eIRB system to ensure that all activities involving human participants would be in compliance with the Common Rule and FAA Order 9500.25C.

Researchers at the Technical Center developed the eIRB system with the goal of modernizing and streamlining the process of submitting protocols for IRB review and protecting participants' PII at the Technical Center. Researchers can register their protocol with the local Technical Center IRB, which then generates a PI folder where the PI of a project can store and organize any documentation that is relevant to the project. The idea behind this is that greater organization of sensitive project documents will make it more likely that participant PII will be adequately protected. The PI folder also contains templates that will assist PIs in completing test plans and informed consent documentation. Within the eIRB system, PIs can complete their IRB application form, which must be submitted in its entirety prior to the beginning of a research or test and evaluation activity. The eIRB system is also used to submit the application form, informed consent documents, and any other relevant documentation such as surveys or questionnaires for approval by the local Technical Center IRB chair. If a PI needs to make revisions to their final IRB submission, revisions can also be made using the eIRB system. Once an IRB submission is approved by the local Technical Center IRB chair, the research or test and evaluation activity can move forward.

2 Purpose

The purpose of this study was to evaluate the usability of the new eIRB user system. In this assessment, the focus was to examine how effectively and efficiently the eIRB allows its users to register a hypothetical protocol, populate an IRB application form for the hypothetical protocol, and submit the application form and other relevant documents for IRB review.

3 Methods

3.1 Participants

Participants were nine federal employees from the Technical Center, the Civil Aerospace Medical Institute (CAMI), and the Department of Transportation (DOT) Volpe Center. The participants were recruited via an email stating that the Human-Systems Integration (HSI) branch was seeking participants who conduct or may conduct research involving human participants. The participant recruitment email provided a description of the study and specified the study's timeframe as well as the modality of participation. Those interested in participating were instructed to contact the study's researchers to arrange a participation session. Of the nine participants, seven reported that they have previously submitted proposals to the IRB. A total of nine participants were included in this study.

Participants in this research represent a range of experience levels when it comes to IRB submission, including both novices and experts. A novice in this study is someone who has not submitted a protocol to the local Technical Center IRB previously, but who may in the future. An expert is someone who has submitted a protocol to the local Technical Center IRB previously or someone who has been a member of the IRB review committee. This range of experience helps capture diverse perspectives and usability challenges across various user types. Those who were members of the IRB review committee are essential for understanding how the eIRB system would benefit the existing research submission process.

3.2 Equipment

The study took place remotely via Zoom. For each session, participants joined a pre-scheduled Zoom meeting and shared their application window as they navigated through the eIRB interface. To complete this study, participants were required to have a computer with stable internet connection, and access to a microphone.

3.2.1 Software

The eIRB system was constructed with Microsoft Power Apps. Participants were able to access the interface using a link that was sent to their FAA or DOT email address. Upon accessing the system, participants were instructed to share their Zoom application window so that the researchers could observe the participants' interaction with the system. Participants interacted with three pages of the system including the Registration page (see Figure 1), the IRB Submission Form Fill page (see Figure 2 and Figure 3), and the Submit Protocol for IRB Review page (see Figure 4). Participants reviewed two automated emails, the first was received following the initial registration of their protocol (see Figure 5) and the second was received after submitting a final revision of their protocol. Participants also reviewed a SharePoint folder, created to store the contents of their submission, referred to as the PI folder (see Figure 6).

3.2.1.1 Registration Page

The purpose of the Registration page (see Figure 1) is to allow participants conducting research with human participants to register their protocol with the local Technical Center IRB. Participants were guided through the registration page where they entered a research project title as well as their first and last name. The system was designed so that a user's FAA email would automatically populate in the designated area. If their email address did not automatically appear, participants were instructed to use the email search bar. Once the registration page was completed, participants were instructed to select the **Click Here** button, as seen in part b) of Figure 1. Participants were told that this would establish a OneDrive folder within the eIRB for

that PI and the folder would contain required documentation for a final submission to the local Technical Center IRB chair and reviewers.

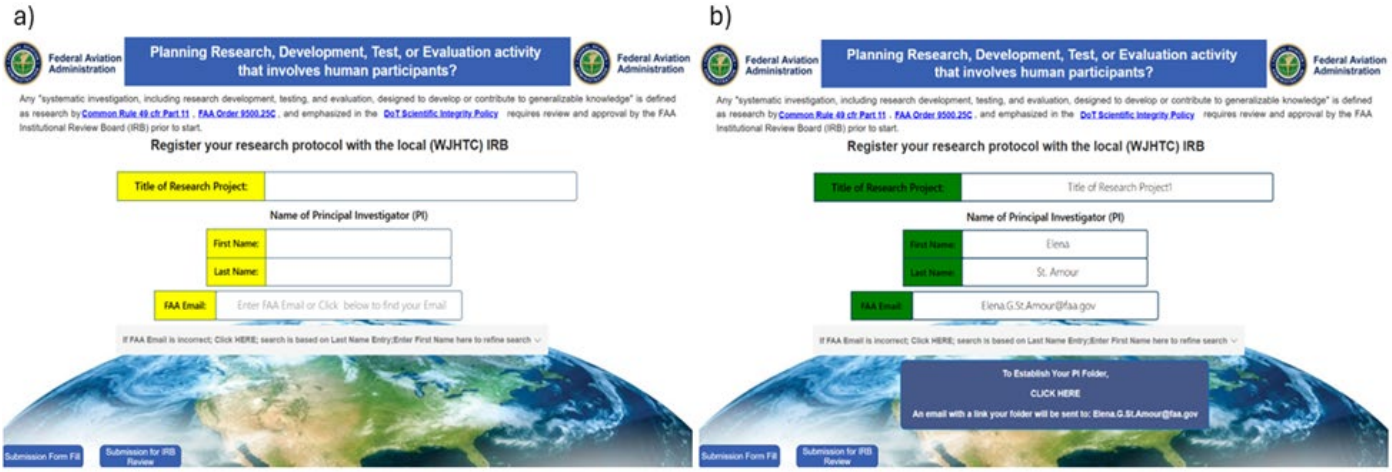


Figure 1: Registration page (a) before and (b) after completing text fields

3.2.1.2 IRB Submission Form Fill Page

Participants used the IRB Submission Form Fill page to complete the IRB submission form; one of two required documents that are submitted to the local Technical Center IRB chair and reviewers. Participants were guided through the IRB Submission Form Fill page and completed several tasks including selecting their project title, completing short-answer and long-answer text fields, using a date picker, selecting yes/no dropdowns, creating an electronic signature, and using speech-to-text to complete long-answer text fields. Prior to selecting a project title, the short-answer text fields, date pickers, and yes/no dropdowns were hidden. However, the long-answer text fields remained accessible.

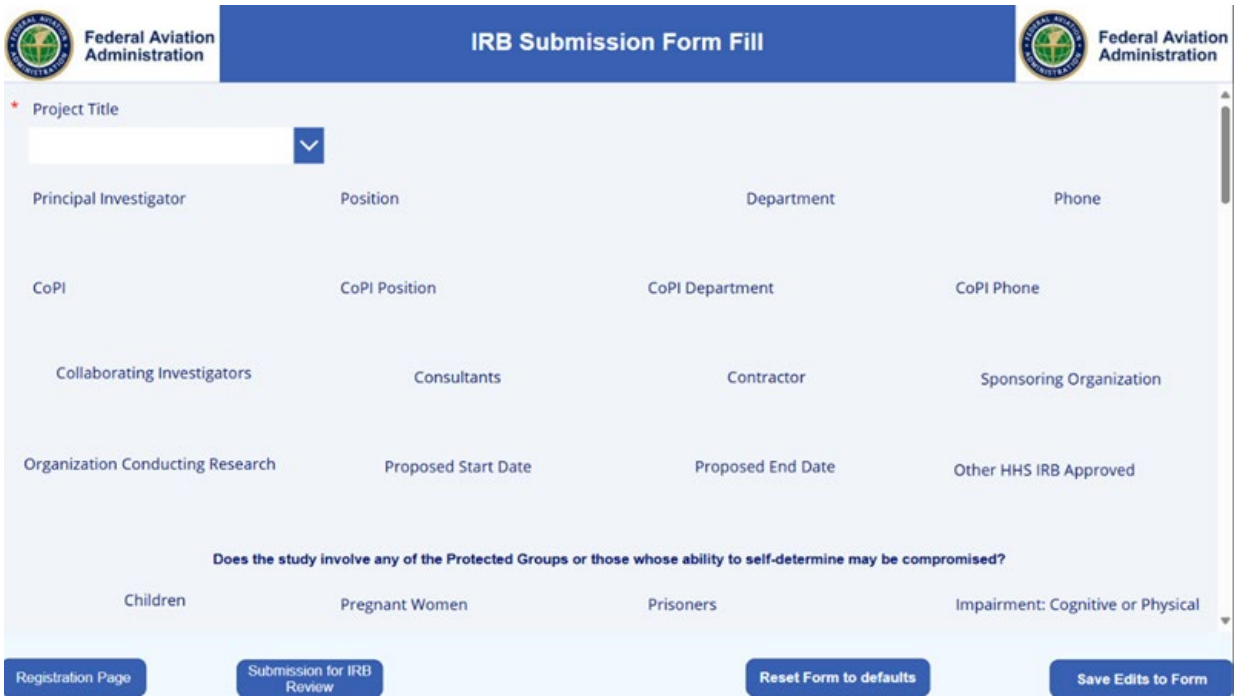


Figure 2: IRB Submission Form Fill page before selecting project title

The short-answer text fields, date picker, and yes/no dropdowns became available once the participant selected their project title (see Figure 3). Upon successful completion of the form, participants were instructed to save their edits, which would then populate the submission form in their PI folder.

Figure 3: IRB Submission Form Fill page after selecting project title

3.2.1.3 Submit Protocol for IRB Review Page

The Submit Protocol for IRB Review Page (see Figure 4) was created for participants to submit relevant research documentation for the local Technical Center IRB to review. On this page, participants are required to submit the Submission form which was filled out using the IRB Submission Form Fill page and a copy of the Participants Informed Consent form. The Submission Form is automatically populated following the selection of a project title, participants were guided through selecting the relevant project title for submission and uploading the Informed Consent form. On this page, participants were told they could also upload surveys, interview forms, questionnaires, or any other relevant research documentation.

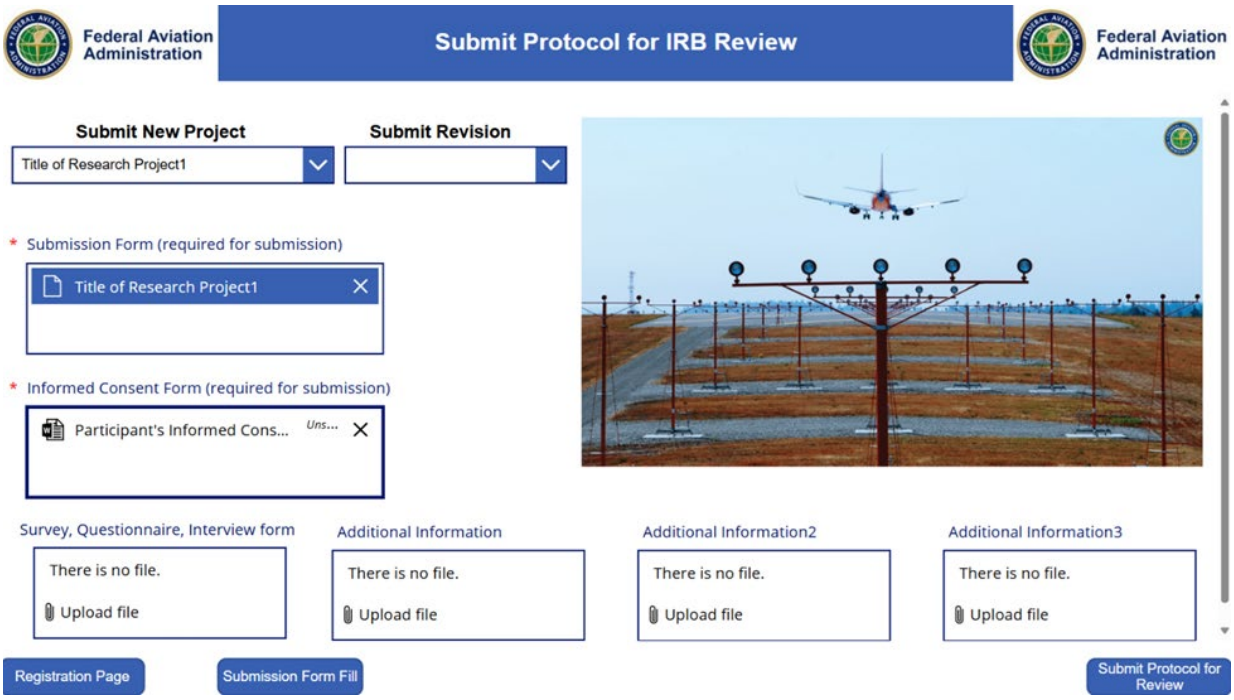


Figure 4: Submit Protocol for IRB Review page with completed protocol

3.2.1.4 Automated Emails

Throughout each session, participants received two automated emails. The first automated email (see Figure 5) was sent following the initial registration of their research protocol. This email included a link to the participant's PI folder, information about documents within the PI folder, and information on documents required in the final submission. The second automated email was sent following the submission of required documentation. The second email was designed to serve as confirmation that a final protocol or protocol revision was successfully submitted.

Thank you for registering your research protocol with the Electronic IRB submission interface.

This interface is designed to streamline the protocol submission, review, and approval process. The site affords the secure archiving of the protocol, approvals, and signed informed consent forms for the required three (3) years post project completion.

You will need to access your PI folder, *Electronic Institutional Review Board (eIRB) Interface Usability Assessment* Click here

Your folder contains the following documents and folders:

1. Informed Consent Form Templates (folder)
   - Participant's Informed Consent Form
   - Investigator Obtaining Participant's Informed Consent Form
2. Signed Informed Consent Forms (folder)
3. FAA IRB Process and Relevant Legal Definitions
4. Description of Volunteer Participation/Test Plan Form

If any of the above documents or folders do not immediately appear, refresh the page.

You will need to complete and submit the following documents for your protocol to be reviewed:

1. FAA Local IRB Submission Form (accessible via the "IRB Submission Form Fill" screen)
2. Participant's Informed Consent form
3. Any surveys or questionnaires being administered (if applicable)

Upon completion of the necessary documents, submit them on the "Submit Protocol for IRB Review" screen.

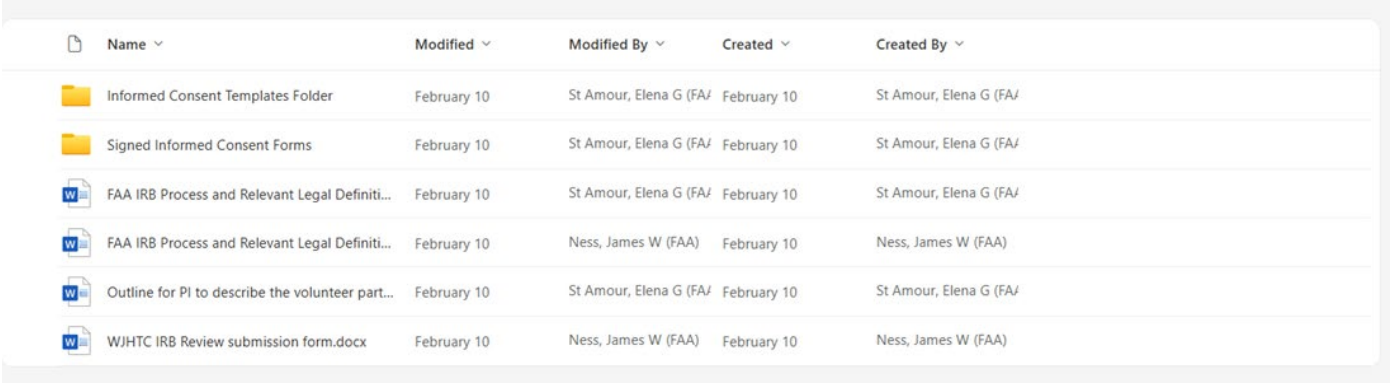
If you have any questions or concerns, please address them to me at james.w.ness@faa.gov or contact me on Teams. I am here to support and assure your project milestones.

All the best,
Jim

Figure 5: Automated email sent following registration of protocol

3.2.1.5 PI Folder

Following the registration of their hypothetical protocol, participants received an automated email containing a link to their PI folder within OneDrive. The PI folder contains a subfolder for the informed consent form template, a subfolder for signed informed consent forms, an in-depth description of the FAA IRB process, an outline instructing the PI of how to describe their project (similar to a test plan and may be useful in filling out the long-answer text fields on the IRB Submission Form Fill page), and a blank copy of the submission form for a protocol. Upon saving edits made on the IRB Submission Form Fill page, the copy of the submission form for a protocol is updated as both a Microsoft Word document and as a PDF. When participants were ready to submit the relevant documentation for final review by the local Technical Center chair or other reviewers, their PI folder had to be added as a shortcut to their OneDrive in order to be accessed by the File Explorer. If users have surveys, interview forms, questionnaires, or other relevant documentation that they wish to submit using the eIRB system, those documents must be added to the PI folder in order to be uploaded.



Name	Modified	Modified By	Created	Created By
Informed Consent Templates Folder	February 10	St Amour, Elena G (FAA	February 10	St Amour, Elena G (FAA
Signed Informed Consent Forms	February 10	St Amour, Elena G (FAA	February 10	St Amour, Elena G (FAA
FAA IRB Process and Relevant Legal Definiti...	February 10	St Amour, Elena G (FAA	February 10	St Amour, Elena G (FAA
FAA IRB Process and Relevant Legal Definiti...	February 10	Ness, James W (FAA)	February 10	Ness, James W (FAA)
Outline for PI to describe the volunteer part...	February 10	St Amour, Elena G (FAA	February 10	St Amour, Elena G (FAA
WJHTC IRB Review submission form.docx	February 10	Ness, James W (FAA)	February 10	Ness, James W (FAA)

Figure 6: PI folder for protocol gone through initial registration

3.3 Materials

3.3.1 Informed Consent

The day before their selected study session, participants were emailed a copy of the informed consent statement for review (Appendix A). The informed consent statement described the study as well as participant rights and involvement. Signing the informed consent document indicated that participants voluntarily consented to participating in this study. Participants were given time to ask questions, read, and sign the informed consent statement during their participation session.

3.3.2 Questionnaires

Following each study session, participants completed the System Usability Scale (SUS) to assess the perceived usability of the system (Appendix B). The SUS is a system-independent, industry standard tool that is used both commercially and throughout the federal government in assessing the usability of a system. The SUS is a ten-item scale that gives a global view of subjective elements of usability. Ultimately, the SUS yields one single score from 0 to 100 that is meant to be representative of the overall usability of a system (Brooke, 1996). A higher score is indicative of higher usability. Previous literature determined that a SUS score of 68 or below may be considered below average and a SUS score of 68 or higher may be considered above average (Sauro, 2011).

Participants also answered a series of rating scale questions to gauge their opinions of the eIRB system and its functionality following their study session (Appendix C). After completing the rating scale questions, participants were given one final opportunity to ask questions or provide comments and suggestions about the eIRB system (Appendix C).

3.4 Data Collection

3.4.1 Schedule of Events

Each participant attended one study session, either in the morning or the afternoon. Each session was slotted to last a maximum of three hours.

Table 1: Morning Study Session Schedule

Time	**Event**
0900-0930	In-brief presentation, review of informed consent form
0930-0945	Break (if desired)
0945-1045	eIRB system navigation/task completion
1045-1100	Break (if desired)
1100-1200	Debrief, final questionnaire completion

Table 2: Afternoon Study Session Schedule

Time	**Event**
1300-1330	In-brief presentation, review of informed consent form
1330-1345	Break (if desired)
1345-1445	eIRB system navigation/task completion
1445-1500	Break (if desired)
1500-1600	Debrief, final questionnaire completion

3.4.2 Procedure

The day before their selected study session, participants were emailed a copy of the informed consent statement for review (Appendix A). At the beginning of each study session, participants were briefed on the purpose of the study, the study session schedule (see Table 1 and Table 2), the extent of their involvement throughout the session, and were given time to read and sign the informed consent. At the end of the in-briefing, participants were informed that the study session was going to be recorded via Zoom so that they had the option to turn their cameras off if they did not want their video to be recorded. Each study session was recorded via Zoom to give the researchers the opportunity to review any comments or questions made about the eIRB system during the session.

After the in-briefing, participants were offered a short break. Participants were then given access to the eIRB system using a Power Apps link that was sent to their FAA or DOT email address. Upon accessing the eIRB system, participants were required to share their Zoom application window so that the researchers could view the participant's screen as they completed a series of four tasks and several subtasks. These tasks included registering a protocol with the local Technical Center IRB using the Registration Page, populating an IRB submission form using the IRB Submission Form Fill page, submitting relevant documentation for final review by the Technical Center IRB chair using the Submit Protocol for IRB Review page, and submitting a protocol revision also using the Submit Protocol for IRB Review page (Appendix D).

Prior to the beginning of each study session and at the conclusion of each of the four overall tasks, participants were encouraged to share their thoughts, feelings, questions, and confusions pertaining to any aspect of each task as well as about the eIRB system. Participants were also reminded that the focus of the research was on how users interact with the system, and not the participant's individual performance of tasks. Throughout each task, participants were prompted to indicate their anticipated next action and to explain the steps they would take to execute it. If participants took an incorrect action or did not know what to do next, they were provided with a series of actions to complete. At the conclusion of each task, researchers asked for clarification on thoughts, feelings, and actions from participants who did not provide details surrounding their uncertainty while completing tasks. In Appendix D, the researcher prompt indicates points where participants were verbally prompted to share their insights on next steps in the overall task and system navigation.

Following the completion of all four tasks, participants were de-briefed and asked to share any final thoughts, feelings, confusions, or questions about anything that they experienced while navigating the eIRB system. Researchers stopped recording the Zoom session and administered the SUS (see Appendix B), a series of rating scale questions, and one final open-ended opportunity to share any comments about the eIRB system (see Appendix C). Participants were dismissed following the completion of all required questionnaire questions.

4 Results and Discussion

4.1 Participant System Usability Scale Ratings

Over the course of the evaluation period, nine SUS responses were received, and are listed below in Table 3. Appendix B lists a blank version of the questionnaire. The average SUS rating for this evaluation was 76.9, which is above the average score of 68 described in Section 3.3.2.

Table 3: eIRB System Usability Scale Ratings

Completion Date	**Participant #**	**SUS Score**	**Do you have any questions, comments, or suggestions regarding the electronic IRB interface? (optional)**
02/21/2025	1	67.5	[No response provided]
03/05/2025	2	70.0	Overall, I feel that the interface is easy to understand with the small exception of overall design of the system. I Believe that some of the tabs could be moved around to be easier to find. Maybe moving the tabs towards the top of the form and have them follow the user down the page as they scroll. Other than that I think the process was smooth and instructions were clear. The information was easy to add and there were no known issues that came up during the uploading and creating documents procedures. The system was simple and effective, I think having everything compile to create a one drive file of everything together is a great way to organize files and establish an easy access route for information.
03/06/2025	3	70.0	[No response provided]
03/07/2025	4	92.5	Great way to streamline the IRB process through a Windows Form!
03/07/2025	5	87.5	I don't know that submitting a protocol will be any easier but I think the file tracking and organization will be helpful.
03/13/2025	6	97.5	I think this is a nice interface and will speed up the process of submitting IRBs.
03/14/2025	7	85.0	I think the interface is easy to use and quite intuitive. I think maybe some definitions about the buttons on the bottom that are always available would be helpful in case they are not intuitive to others but overall a once though with this interface would take care of that. Also training with video etc, or a diagram that explains all of the functions as a visual that someone can print out or save as a PDF would be helpful too. Really a great idea and makes the whole process more efficient!
03/14/2025	8	90.0	Just a small training session to showcase the process of submitting the documents for IRB approval.
03/17/2025	9	32.5	I think that once you did it once, it would be alot easier. Without help, I would have been confused about the flow and some of the steps I would have needed to take.
Average:		**76.9**	

4.2 Participant Follow-Up Questionnaire

Participants used a Likert scale to rate their level of agreement with each statement regarding the ease of interaction with the eIRB system. A blank version of the questionnaire is listed in Appendix C. Table 4 includes the questions and responses recorded from all nine participants.

Table 4: eIRB System Likert Scale Question Survey Responses

Question	**Responses**
How satisfied are you with the ease of registering a protocol on the "Registration Page" of the eIRB interface?	• Somewhat dissatisfied (1) • Somewhat satisfied (2) • Very satisfied (6)
How easy would it be for you to fill out a protocol submission form using the "Submission Form Fill" screen of the eIRB interface without any instructions?	• Somewhat difficult (1) • Neither difficult nor easy (1) • Somewhat easy (6) • Very easy (1)
How easy would it be for you to upload the necessary files for final protocol submission on the "Submit Protocol for IRB Review" screen of the eIRB interface?	• Somewhat difficult (2) • Neither difficult nor easy (1) • Somewhat easy (3) • Very easy (3)
Compared to the current process for making a protocol submission to the IRB for review, how much easier did you find it to submit a protocol for IRB review with the eIRB interface?	• Neither harder nor easier (3) • Somewhat easier (2) • Much easier (2) • Not applicable/Have not previously submitted to the IRB (2)

4.3 Participant Comments

Participants were asked to express their comments, questions, concerns, and confusions aloud to the researchers. Each study session was recorded via Zoom to accurately capture each participant's comments, questions, concerns, and confusions pertaining to any features or processes affiliated with the eIRB system.

We consolidated participant comments into a spreadsheet (see Appendix E). During each study session, we documented all participant comments pertaining to their interaction with the system. Following the conclusion of all study sessions, we reviewed each participant's session recording

to ensure that all questions, comments, and suggestions to the system were thoroughly documented. Upon analysis, it was evident that we could categorize participant feedback based on its relevance to navigation, functionality, design aesthetic, instructional clarity and wording, and overall user experience. Participants also expressed distinct likes, desired changes, and confusions or questions within each of these categories (See Appendix E).

4.3.1 Navigation

Navigation refers to the movement between the Registration, IRB Submission Form Fill, and Submit Protocol for IRB Review pages of the eIRB system. Navigation also includes moving back and forth between the eIRB system and automated emails sent throughout the protocol registration and submission processes. Throughout the study sessions, several participants noted issues with navigation throughout the different pages of the eIRB system.

Five participants expressed confusion and had questions about navigation following the initial registration of their protocol on the Registration page. The expectation was that after receiving an automated email following their initial registration of a protocol, participants would then navigate to their FAA/DOT email address, read the instructions contained in the automated email, and open their PI folder. After opening their PI folder, participants were then expected to navigate to the IRB Submission Form Fill page from the Registration page. However, during the study sessions, many participants either did not know to navigate to their FAA/DOT email address to find an email with the link to their PI folder or to return back to the Registration page in order to then navigate to the IRB Submission Form Fill page. For participants who successfully returned to the Registration page after opening their PI folder, some were unsure as to whether navigating to the IRB Submission Form Fill page or the Submit Protocol for IRB Review page would be the next step.

Participants also did not recognize that the Registration page was the Home page for the eIRB system. Several participants expressed that having a Back button on the IRB Submission Form Fill page or that having a clearer indication that the Registration page is the Home page would be useful. To navigate back to the Registration page from the IRB Submission Form Fill page, a number of participants selected the browser's Back button rather than selecting the Registration page button.

Based on the above comments, we have several recommendations for improvements that can be made to the system in terms of navigation. **We recommend [1] that the design of the eIRB system should be consistent with user mental models, allowing for greater consistency and a decrease in learning or training times when getting started with the system** (Ahlstrom,

2016). In order to accomplish this in terms of navigation, especially on the Registration page, **we recommend [2] that users are more clearly directed to navigate to their FAA or DOT email address following the initial registration of their protocol.** This instruction could appear on the screen after the user hits the Submit button to initially register their protocol. **Along the same lines, we recommend [3] that clearer instructions should be included in the automated email that users receive upon registering their protocol so that users know to return to the Registration page and subsequently the IRB Submission Form Fill page.**

Lastly, considering that the Registration page serves as the system's Home page, **we recommend [4] adding Back buttons to the IRB Submission Form Fill and Submit Protocol for IRB Review pages to return the display to the latest previous state. We also recommend [5] numbering the steps within the buttons themselves, such as having the IRB Submission Form Fill page button on the Registration page display something like "Step 2 - IRB Submission Form Fill".** There are a number of ways that this confusion can be mitigated, but, in summary, participants noted that there was not enough clarity on the flow of the system, and which steps should be taken in which order.

4.3.2 Functionality

Functionality refers to the operations occurring within each of the eIRB system pages rather than just the movement between each of the three pages. Functionality comments included notes pertaining to system performance, responsiveness, and how the system responded to user actions while on any page. Throughout the study sessions, participants noted several functionality issues with various elements included on the Registration, IRB Submission Form Fill, and Submit Protocol for IRB Review pages of the eIRB system.

Four participants expressed a desire for confirmation messages following important steps when navigating through the eIRB system. For example, participants anticipated that they would receive a confirmation message that their protocol had been successfully registered following completion of their initial registration on the Registration page. Similarly, participants expected to receive feedback upon saving edits to their submission form on the IRB Submission Form Fill page. Participants also expressed a desire to receive a confirmation message within the eIRB system that the final version of their protocol was successfully submitted on Submit Protocol for IRB Review page. After submitting the initial registration and final versions of their protocol, participants received emails confirming these submissions, but participants indicated a preference for receiving these confirmations within the system itself rather than via email.

Further, participants indicated a desire to have the option to use their Personal Identification Verification (PIV) card to sign their submission form on the IRB Submission Form Fill page. As it currently stands, participants must sign this form using an electronic pen, which creates a signature by holding down on the left side of their mousepad to draw (see Figure 7). Participants have control over the thickness and color of their signature. Several participants found this process to be tedious and not an accurate reflection of their true signature, thus the desire to use their PIV card to sign, as signing using a PIV card generates a typed signature and date of signature.

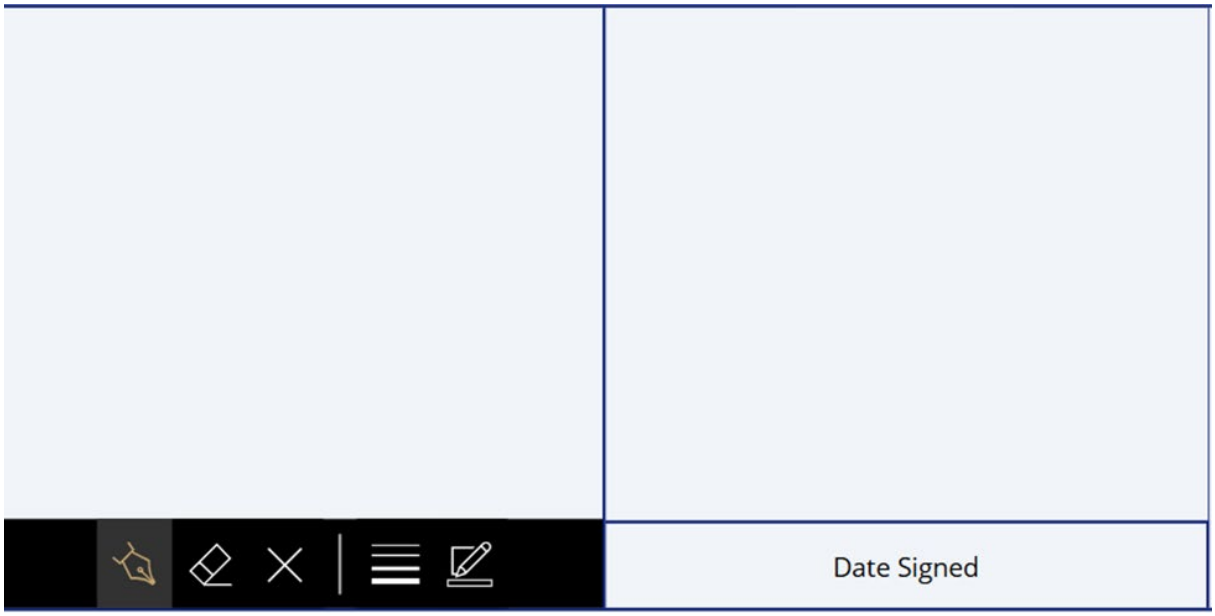


Figure 7: Electronic signature panel on IRB Submission Form Fill Screen

Eight participants expressed confusion as to how to upload files from their PI folder for final submission on the Submission for IRB Review page. The expectation was that participants would sync their PI folder to their OneDrive and add the folder as a Shortcut, thus making their PI folder accessible from the OneDrive section of File Explorer. Once the PI folder was accessible from the OneDrive section of File Explorer, participants could click Upload File and upload the desired documents directly from their PI folder. However, this process was not clear to participants, as they selected Upload File and tried to find the desired document in the Downloads section of File Explorer. Participants believed that the steps for syncing their PI folder to OneDrive and then adding the PI folder as a Shortcut would have been complicated had they not been given the instructions for how to take those actions. Upon being given directions for how to make their PI folder accessible from the OneDrive section of File Explorer, participants were able to successfully upload documents.

Lastly, several participants attempted to examine a preview of their submission form on the Submit Protocol for IRB Review page. Upon doing this, a new window opened with an error message. Currently, participants may review the forms that they are about to submit by navigating to their PI folder and opening the forms that way. Participants expressed a desire to be able to review a preview of their documents within the eIRB system prior to making a final submission. By having the ability to review documents within the eIRB system, users would not need to take the additional step of opening their PI folder to make a final assessment of the documents that they wish to submit.

Based on the comments from participants, we have numerous recommendations for improving the functionality of the eIRB system. **We recommend [6] the implementation of confirmation messaging following critical actions taken using the eIRB system, such as after registering an initial protocol, saving changes on or navigating away from the IRB Submission Form Fill page, and following the submission of the final version of a protocol on the Submit Protocol for IRB Review page.** For example, if users accidentally navigate away from the IRB Submission Form Fill page without saving their entries, submit an initial registration with a typo in the email address field, or submit the final version of a protocol with an incorrect file attached, there is no warning or pop-up to prompt the user that data will be lost or to review their work. If any entries resulting in changes in stored data or system operations, confirmation should be required before implementing the action (Ahlstrom, 2016).

While this may not be possible due to development constraints in Microsoft Power Apps, **we recommend [7] giving users the ability to use their PIV cards to electronically sign their submission form on the IRB Submission Form Fill page.** This would be most consistent with user mental models, as other forms and systems within the FAA and DOT allow users to electronically sign documents using their PIV card. Alternatively, to minimize user effort necessary to complete the task, it may be useful to allow users to type their signature rather than draw their signature.

The greatest source of confusion and displeasure for participants surrounded the process of uploading files from their PI folder for final submission on the Submit Protocol for IRB Review page. To allow the task to be carried out as intended by the development team, **we recommend [8] providing thorough step-by-step instructions for how to complete the task.** Currently, the instructions to complete this task exist within the PI folder and there are no instructions given directly on the Submit Protocol for IRB Review page. To minimize user effort in locating these instructions, as well as to make them more accessible for users, the instructions for uploading files could exist in a Help window on the Submit Protocol for IRB Review page.

Relevant to system functionality, we also recommend [9] allowing users to view previews of their submission form and other uploaded documents directly on the Submit Protocol for IRB Review page. While this may not be possible due to constraints within Microsoft Power Apps, user effort would once again be minimized as users would not be required to navigate to their PI folder to preview the documents that they wish to submit, thus reducing the number of keystrokes required to complete the desired task (Ahlstrom, 2016).

4.3.3 Design Aesthetic

Design aesthetic refers to the visual style of a system, as well as the system's look and feel, which played a key role in shaping the users' first impressions and emotional response to the system. Throughout the study sessions, participants commented on the eIRB system's overall design aesthetic, specifically focusing on the layout and graphical elements used on the Registration and IRB Submission Form Fill pages.

Several participants expressed that it was not apparent to them that the Click Here button on the Registration page was the button that they were meant to press. Currently, the Click Here button on the Registration page is darker in color and contains more text than other buttons on the page (see Figure 8). Participants indicated a desire to make the Click Here button, as well as the other buttons on the Registration page, look more like buttons by making them all the same color and give them more cushion so that they look raised rather than flat.

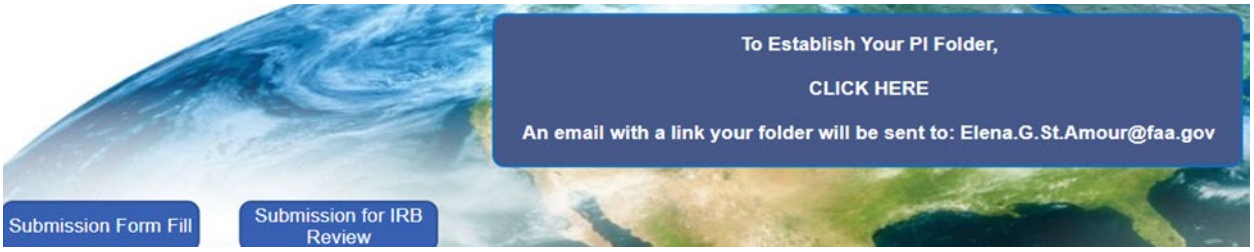


Figure 8: Click Here button and other buttons on Registration page

Participants also expressed that the Registration page, particularly the top portion of the Registration page, was a little noisy, which made the Registration page difficult to process. Currently, the top of the Registration page contains the two FAA logos, the title of the page, and information and links that are relevant to demonstrating the importance of submitting research protocols to the IRB (see Figure 9). Participants made several suggestions for reducing the amount of noise on the Registration page, such as removing the blue banner behind the page title, removing one of the two FAA logos, and information and links to the bottom of the page rather than leaving them at the top.

Figure 9: Top of Registration page

On the IRB Submission Form Fill page, the main comment that participants made was that when a project title is not selected, text boxes for the short-answer text fields, the date pickers, and yes/no dropdowns do not exist (see Figure 2). Prior to a project title being selected, the titles for the short-answer text fields, date pickers, and yes/no dropdowns appear to be floating on the page. Only once a project title is selected do the white boxes for each of those fields appear (see Figure 3). For participants, the lack of boxes prior to the selection of a project title made the page feel "chaotic" and "dizzying", which made it less pleasant to engage with the system.

Based on participant comments pertaining to design aesthetic, we have several recommendations for improving the design of the eIRB system. **We recommend [10] that all push buttons used in the application have a consistent appearance in terms of shape, size, and color, and that all push button text labels are made shorter** (Ahlstrom, 2016). Push button labels are meant to describe the result of pressing the button without containing lengthy amounts of text. Currently, there are several buttons throughout the system that look unlike each other and contain longer text labels (such as the example in Figure 8), making the buttons not quite look like buttons. To make the buttons look more like buttons rather than flat text boxes, adding cushion to make them look more three-dimensional could be beneficial.

In addition, we recommend [11] simplifying the design of the screens and minimizing information density, particularly on the Registration page. Users' natural scanning order will typically be from left to right and top to bottom (Ahlstrom, 2016). Currently, the top of the Registration page contains two FAA logos, the title of the page, and information and links that are relevant to demonstrating the importance of submitting research protocols to the IRB, while the text fields that users need to fill out exist below that information. While the information and links that are relevant to demonstrating the importance of submitting research protocols to the IRB are all important, they are not essential to the user when visiting the Registration page. To simplify the Registration page and allow users to focus on what is most essential, that additional information can be moved to the bottom of the page.

Finally, we have recommendations in terms of design aesthetic pertaining to the appearance of the short-answer text fields, date pickers, and yes/no dropdowns on the IRB Submission Form Fill page. **We recommend [12] that throughout the system, especially on the IRB**

Submission Form Fill page, fields should have a distinctive, consistent appearance that aligns with user mental models and expectations. Even if there is no title selected, the fields should be present on the page to allow users to better orient themselves and to reduce clutter and confusion upon interacting with elements on the page.

4.3.4 Instructional Clarity and Wording

A separate category was created for instructions and wording as a significant number of comments from participants pertained to verbiage used throughout the eIRB system. These comments specifically focused on clarity of language and readability of instructions provided throughout the system.

Participants primarily commented about instructions and wording used on the IRB Submission Form Fill page rather than on the Registration or Submission for IRB Review pages. Particularly, participants felt that instructions for several of the long-answer text fields lacked clarity and required elaboration. For example, participants felt that there were not sufficient instructions given for what input would be expected for the Problem Statement field compared to the other long-answer text fields on the page (Figure 10). Currently, for the other long-answer text fields on the page, guidelines are given to demonstrate what information should be entered for the particular field. Participants recommended giving an example of a problem statement or using language that instructs the user on how to respond to the prompt.

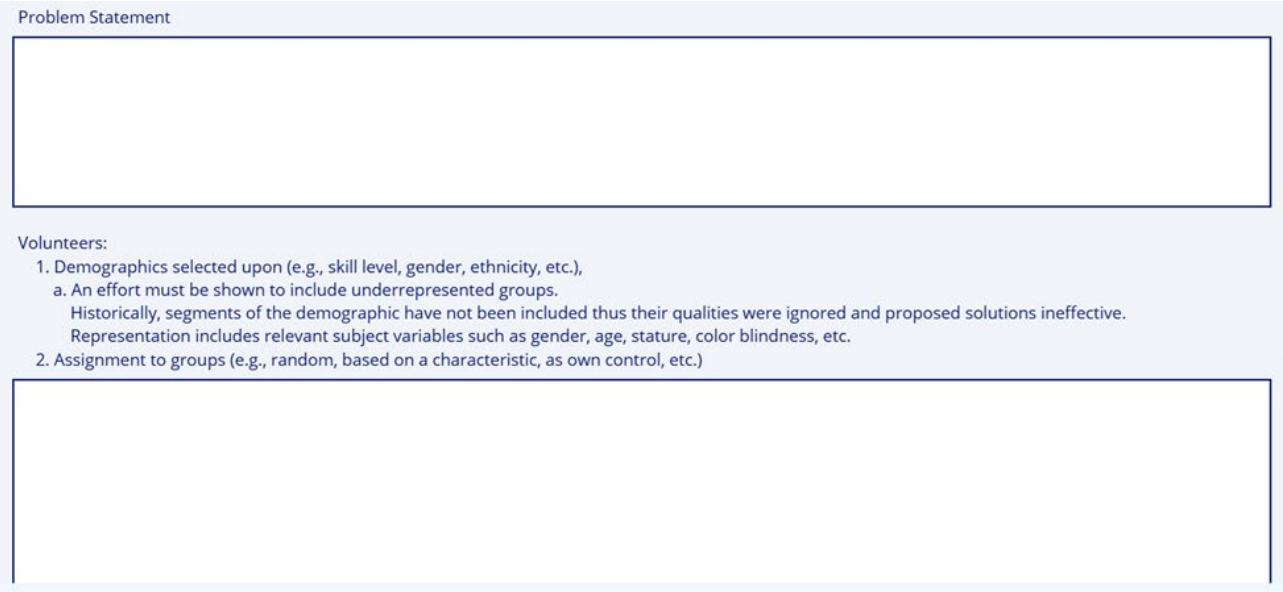


Figure 10: Problem Statement and Volunteers text fields

Participants also expressed confusion about the statement "An effort must be shown to include underrepresented groups" under the Volunteers long-answer text field on the IRB Submission Form Fill page (Figure 11). Specifically, participants were uncertain if they were expected to provide the total number of participants from underrepresented groups that they were recruiting, if they were supposed to say yes or no about if an effort was made, or if they were to detail how they would be putting forth the effort to include underrepresented groups. Two participants stated that these instructions felt more like guidelines than actual instructions, and that direct and specific language should be used to indicate what exactly would be expected of a user.

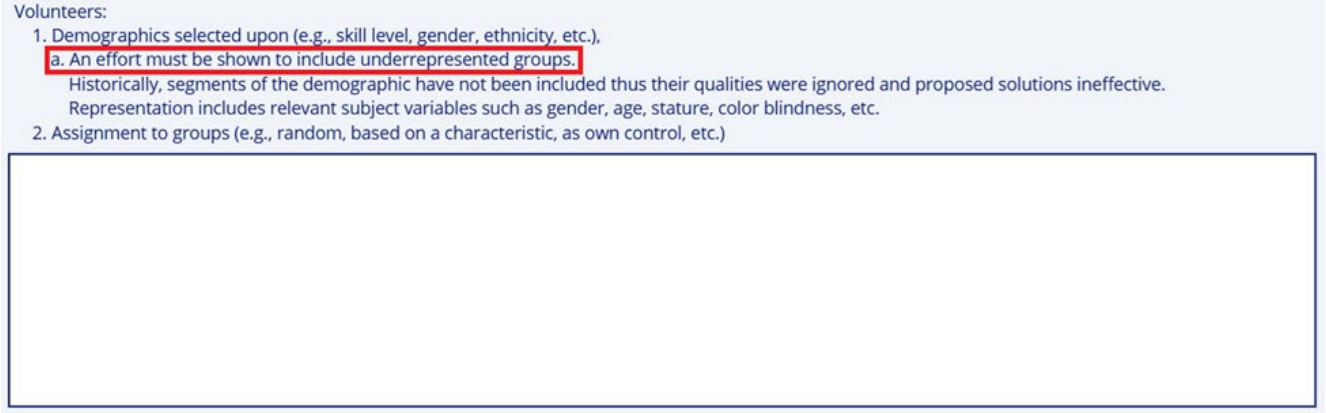


Figure 11: Volunteers long-answer text field instruction that confused participants

Lastly, participants indicated confusion with the wording used in the Results/Data Management long-answer text field on the IRB Submission Form Fill (Figure 12). Several participants indicated that they were unsure of what the "Not 'The Data Management Plan'" statement meant, as they hadn't realized that there was a separate Data Management Plan document that is different from the Results/Data Management section of the IRB submission form. One participant suggested that this should be reworded to elaborate on the fact that information from the Data Management Plan document would not be expected to be entered in the Results/Data Management section.

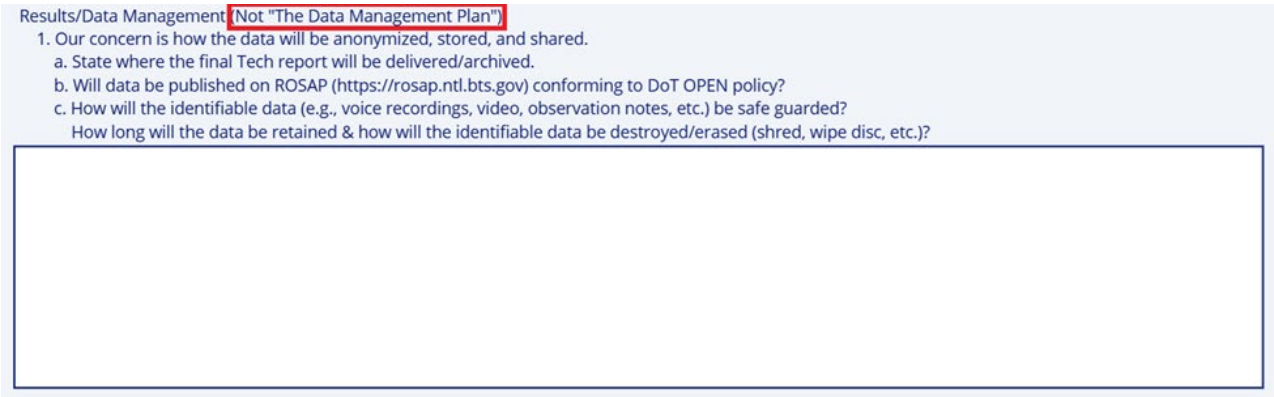


Figure 12: Results/Data Management long-answer text field instruction that confused participants

We recommend [13] that the verbiage used should be kept simple, consistent, and direct to minimize confusion and to indicate what exactly is expected of users when completing a specific task. Participants primarily indicated confusion about the instructions provided on the IRB Submission Form Fill page. For example, there are guidelines provided for what is expected in each long-answer text field on the IRB Submission Form Fill page aside from the Problem Statement field. It is recommended that some guidance be provided to direct users as to what is expected in the Problem Statement field. We recommend that further clarification be provided in describing what type of effort must be shown to include underrepresented groups in the Volunteers. Further, for users who do not know that there is a different Data Management Plan document aside from what is expected to be described in the Results/Data Management field, **we recommend [14] that the instructions should be reworded to elaborate on what information is expected to be entered in the Results/Data Management section that differs from what is included in from the Data Management Plan document.**

4.3.5 User Experience

User experience (UX) refers to the overall intuitiveness and satisfaction a person has when interacting with a system. This includes how easy, efficient, and enjoyable it is for participants to complete tasks. Throughout the study sessions, participants made note of positive and negative aspects of the eIRB system in terms of UX.

This feature is not necessarily specific to the eIRB system, but participants expressed that they liked the fact that speech-to-text could be used on the long-answer text fields on the IRB Submission Form Fill page (Figure 13). To enable speech-to-text, participants were instructed to press the Windows and H keys at the same time. When the speech-to-text pop-up appeared, participants were then instructed to click the microphone icon and begin speaking. Participants found that especially for sections that require more information, having speech-to-text as an

option could simplify filling out the required long-text fields. While users would still need to proofread what is entered through speech-to-text, participants felt strongly that this would save them time when completing the required documentation for IRB submission.

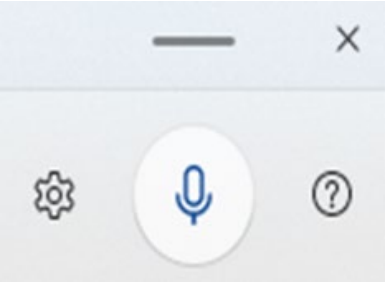


Figure 13: Speech-to-text pop-up on IRB Submission Form Fill page

While participants were largely happy with the UX of the eIRB system, an area that they felt could use improvement was the difficulty of uploading files, which was also discussed in Section 4.3.2. While participants didn't find the actual process of uploading files to be difficult, they found that the process of preparing the documents for upload was not intuitive. Specifically, it was not intuitive to many participants that a shortcut for the PI folder must be added to OneDrive prior to attempting to upload files. Participants stated that if they were not told to take that step, that they felt as though they would not have figured it out themselves. When prompted to demonstrate uploading a file for final submission on the Submit Protocol for IRB Review page, most participants clicked Upload File and uploaded a document from their downloads in File Explorer rather than adding their PI folder as a shortcut in OneDrive. Several suggestions were made, including adding instructions as to how to complete this step in the initial registration email, adding a Help window where users could find instructions, and adding instructions directly to the Submit Protocol for IRB Review page itself.

Overall, participants were pleased with the UX of the eIRB system. **We recommend [15] that instructions should be provided throughout the system in order to minimize confusion and user effort as they complete the tasks necessary to produce an IRB protocol submission.** In order to prevent the system from becoming too cluttered with instructions, **we recommend [16] having a Help window where instructions for completing various steps are stored. We also recommend [17] designing training content that users who are new to the system can use to follow along with as they prepare their submission.** The training content can be housed on a separate website or application and can be made accessible to users at any time.

5 Conclusions

The current process for submitting an application, which was established in 1998 when the Technical Center began reviewing IRB submissions, consists of a significant amount of correspondence between the Principal Investigator and local IRB chair. This process has introduced inefficiencies and delays in moving forward with research or test and evaluation activities. Additionally, the current process has contributed to the disorganization of important documentation relevant to research and test and evaluation protocols as well as inadequate protection of human participants. This study sought to evaluate the usability of the eIRB system, which is the intended replacement for the current process for submitting protocols to the local Technical Center IRB.

We evaluated the usability of the three pages included in the system, the Registration page, the IRB Submission Form Fill page, and the Submit Protocol for IRB Review page. This was done by having participants complete four overall tasks: registering a protocol with the local Technical Center IRB using the Registration page, populating an IRB submission form using the IRB Submission Form Fill page, submitting relevant documentation for final review by the local Technical Center IRB chair using the Submit Protocol for IRB Review page, and submitting a protocol revision also using the Submit Protocol for IRB Review page.

We sought to measure the usability of this system by utilizing the think-aloud protocol, as we encouraged participants to verbalize their thoughts, feelings, questions, and concerns as they navigated the eIRB system to complete the aforementioned tasks. Following the completion of the four overall tasks, participants were instructed to complete the SUS to assess the perceived usability of the system. Participants also responded to a series of additional rating scale questions to further gauge their opinions of the eIRB system and its functionality.

Our participant group consisted of employees from the Technical Center, CAMI, and DOT at the Volpe Center. Over half (7/9) of the participants in this study reported having prior experience with the IRB before, whether that be in terms of protocol submission or in participating as part of the IRB review committee. We found that none of the participants who had prior IRB experience found the process for making a protocol submission to the local Technical Center IRB using the eIRB system more difficult than the current submission process.

We found that the overall user experience of this system was good, as the average SUS score for this system indicated above-average usability. At least two-thirds of the participants in this study were satisfied with the ease of completing the four overall tasks on each of the pages in the eIRB system. A critical difference between this study and the typical expected use of this system is the

duration of time spent using the system. The participants in this study completed each of the four tasks sequentially and spent approximately one hour using the system from start to finish. While the time spent registering the protocol initially on the Registration page was realistic, the time spent on the IRB Submission Form Fill and Submit Protocol for IRB Review pages was not accurate, as users would likely need to spend more time filling out the long-answer text fields and required documentation for final IRB review. It is possible that a more extensive study would uncover different opinions about the system, as users would be spending a greater length of time navigating through the system as well as back and forth between the required documentation and the system itself.

While the overall user experience of this system was good according to the average SUS score for this group of participants, participants reported several areas of improvement for this system. We categorized participant comments based on their relevance to navigation, functionality, design aesthetic, instructional clarity and wording, and overall user experience. We further categorized participant comments based on likes, desired changes, and confusions or questions. Each of these categories had a significant number of comments focused on desired changes, indicating that despite satisfaction with the system, there are certainly areas where the system can be improved. The highest number of desired changes and questions or confusions occurred on the IRB Submission Form Fill and Submit Protocol for IRB Review pages.

There are several considerations that must be made in the design and implementation of the eIRB system, especially considering the importance of remaining in compliance with federal regulations regarding the protection of participant PII and data management. The design of a system that allows users to easily and efficiently accomplish their goals is only half the battle; enforcement of compliance with the Common Rule and FAA Order 9500.25C for those engaging in research or test and evaluation activities involving human subjects must occur in order for eIRB system to serve its true purpose.

5.1 Next Steps

Following the review of questionnaire results and comments from participants, the researchers will begin developing prototypes of ways in which the current design and functionality of the eIRB system can be improved. Upon implementation of the recommendations for improvement of the design and functionality of the eIRB system, researchers will conduct another usability assessment of the newly proposed next version with a larger, more diverse participant pool in order to gain as much feedback as possible. Specifically, the researchers will aim to include more test and evaluation personnel than were included in the current study as well as increase the total

number of participants. The researchers will also begin designing training content to assist new users in becoming acclimated to the eIRB system. The researchers will also continue to refer to the Human Factors Design Standard (HFDS) to ensure that recommendations are compliant with human factors design criteria oriented to the needs of the FAA mission and systems (Ahlstrom, 2016).

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A Informed Consent Statement

Informed Consent to Participate in Research Study

Electronic Institutional Review Board (eIRB) Interface Usability Evaluation

Principal Investigator (PI): Elena St. Amour, Engineering Research Psychologist, Federal Aviation Administration, William J. Hughes Technical Center, Human-Systems Integration Branch, ANG-E5B.

Invitation to Participate in Research Study

Elena St. Amour invites you to participate in a research study about the electronic Institutional Review Board interface at the William J. Hughes Technical Center for Advanced Aerospace. This study is sponsored by the William J. Hughes Technical Center representative to the IRB Chair.

Summarized Key Information

1. Your participation in this study is completely voluntary, and it is your choice whether to participate or not. You may decline or withdraw your participation in the study at any time. The choice to decline or withdraw from the study will not cause any penalty or loss of any benefit to which you are entitled.
2. The purpose of this research is to assess the usability of the new electronic Institutional Review Board (eIRB) interface. The participant is expected to register a hypothetical research protocol with the William J. Hughes Technical Center local IRB, fill out an IRB application form for their hypothetical protocol, and submit their application form (amongst other relevant documents) for IRB review. Participants are also expected to fill out the System Usability Scale (SUS) based on their experience using the eIRB interface and answer a few other open-ended questions. The expected duration of participation is approximately three (3) hours or less.
3. There are no risks or discomforts which are foreseeable given the nature of the performed actions of the participant and the nature of the context in which the actions are performed.
4. You will not directly benefit from your participation in this study. The only benefit to you is that your feedback will help inform FAA decisions regarding the design and

functionality of the electronic IRB interface for registering and submitting protocols for research involving human participants.

The purpose of the study

The purpose of this research is to assess the usability of the new electronic Institutional Review Board (IRB) interface. In this assessment, the primary focus will be to examine the capacity of the electronic IRB interface to allow its users to effectively and efficiently register a hypothetical protocol, populate an IRB application form for the hypothetical protocol, and submit the application form (amongst other relevant documents) for IRB review.

Elena St. Amour, on behalf of the William J. Hughes Technical Center representative to the FAA IRB Chair, invites volunteers to participate in a research study investigating the usability of new electronic Institutional Review Board (IRB) interface used to submit protocols to the William J. Hughes Technical Center IRB for activities that involve human participants. The goal of the research is to determine if the design and functionality of the electronic IRB interface efficiently and effectively allows practitioners to register and submit protocols for research involving human participants.

Description of participant involvement

You will navigate the electronic IRB interface by registering a hypothetical research protocol with the William J. Hughes Technical Center local IRB for review. Upon receiving an email confirming the establishment of your IRB folder, you will then fill out an IRB application form for the hypothetical protocol and submit the application form (amongst other relevant documents) for IRB review. The test will occur in one session and take no more than three (3) hours. If the session exceeds one hour, breaks will be scheduled every hour or as often as necessary. A questionnaire (John Brooke's System Usability Scale, or SUS, along with a few other open-ended questions) will be administered at the end of the session to gather participant reactions and responses about the electronic IRB interface.

The session will be audio and/or video recorded for subsequent review by the research team. Audio and/or video recordings will capture participant faces as well as verbalized thoughts and responses to the tasks presented in this study. Any audio and/or video recordings will be stored on secure FAA servers, will only be accessed by the research team, and will not be included in the publication of this research project. Further, audio and/or video recording is not a requirement for participating in this study.

No foreseeable risks or discomforts are associated with this research. You will not directly benefit from your participation in this study. The only benefit to you is that your data and feedback will help inform FAA decisions regarding the potential addition of the new electronic IRB submission process in the field. If you decide to participate, please sign this form to show that you want to voluntarily take part. Participation is voluntary. You may refuse to participate before the study begins, discontinue at any time, or skip any questions or procedures that may make you feel uncomfortable, without need to justify your decision and with no penalty or any other adverse consequence.

Audio/video recordings will be made during the study so that the researchers can review relevant events later if needed. These recordings will be stored in a secured location so that only the research team will have access to them.

☐ *I agree to allow my audio/video recordings to be used in briefings about this study presented to others outside the research team.*

☐ *I DO NOT agree to allow my audio/video recordings to be used in briefings about this study presented to others outside the research team.*

Conflict of Interest

The Principal Investigator and the Sponsoring Agency have no known conflicts of interest that would diminish or otherwise influence the procedures, conclusions, and objectivity of this research.

Potential Benefits

You will not directly benefit from your participation in this study. The only benefit to you is that your data and feedback will help inform FAA decisions regarding the design and functionality of the electronic IRB interface for registering and submitting protocols for research involving human participants.

Risks and Discomforts

There are no risks or discomforts which are foreseeable given the nature of the performed actions of the participant and the nature of the context in which the actions are performed. Notwithstanding, the investigator will be vigilant, assessing unforeseeable and unanticipated events, which will be immediately assessed and may result in stopping the study. Any such risk or discomfort will be reported to the FAA IRB WJHTC representative, James Ness (james.w.ness@faa.gov) for a review of the event and determination of continuation of the

research without modification of actions to be performed or the context within which actions are performed.

Compensation

Participants will not receive compensation for participation in this study.

Participant's Rights

You will not lose any legal claims, rights, or remedies by signing this form and by your participation in this research study. The local FAA Institutional Review Board has reviewed this research project under expedited review and found it to be acceptable, according to applicable state and federal regulations designed to protect the rights and welfare of participants in research.

Cost to Participant

You will not incur any costs for participating in the research study.

Confidentiality

The data and information you provide during the course of this research is confidential. No personally identifiable information, data, or statements will be disclosed in any report, briefing, presentation or discussion of the research unless such information is required to be disclosed under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, or otherwise required to be disclosed by law. Information, data, or statements subject to FOIA may be protected from release if it falls within one of the nine FOIA exemptions. Such exemptions include the protection of personally identifiable information (PII) under exemption b (6) when such information would constitute a clearly unwarranted invasion of personal privacy of the individuals involved. However, de-identified information data, or statements may still be disclosed under FOIA. The de-identified data may also be made available to other researchers for research-related purposes only.

The data collected will be stored only by code number, not by name. No names or identities will be released in any research reports, publications, or presentations resulting from this work. Electronic data, including any audio and/or video recordings, will be maintained on secure FAA computers and websites that are accessible only by research team members. Any data collected on paper (e.g., questionnaires) will be secured in a locked file cabinet accessible only by research team members. The de-identified data from the study may be made available to other researchers

for related studies. Your participation in this research study will be kept confidential to the extent permitted by law.

Injury

If there is an emergency, call 911 or call the William J. Hughes Technical Center's Operations Center at x6482 or Security at x5000. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury. The injury incident will be reported to William J. Hughes Technical Center Safety Office (9-ACT-Safety@FAA.Gov) and FAA IRB representative, James Ness (james.w.ness@FAA.Gov). The FAA IRB in collaboration with the Safety Office will investigate and remediate policy and practices as necessary to assure beneficence as described in the Belmont Report.

Voluntary nature of this study / Participation and Withdrawal

Your participation in this study is completely voluntary and it is your choice whether to participate or not. You may decline or withdraw your participation in the study at any time. The choice to decline or withdraw from the study will not cause any penalty or loss of any benefit to which you are entitled. During the study, the principal investigator or research team member will share any new information that develops that may affect your decision to continue to participate. The principal investigator or member of the research team may also terminate your participation in the study at any time if they determine the level of discomfort or risk is above that of minimal risk as defined by the Health and Human Services Office of Research Protection.

If circumstances are such that I choose to withdraw from the study.

☐ You are authorized to retain my de-identified data.

☐ Please destroy all data collected on me or associated to me.

If circumstances are such that the attending researcher withdraws me from the study.

☐ You are authorized to retain my de-identified data.

☐ Please destroy all data collected on me or associated to me.

Contact Information

If you have questions about the study, please ask them before signing this form. You can ask any questions that you have about this study at any time, or after your participation concludes.

For questions, concerns, or complaints about this study, please contact the principal investigator, Elena St. Amour at 609-485-5880. If you feel that you have been treated unfairly, or you have questions regarding your rights as a research participant you may contact the Local Institutional Review Board Representative James W. Ness at 609-485-5537 or the FAA IRB Chairperson Thomas Chidester at 405-954-2700.

Participant's Signature Acknowledging Informed Consent to be in research study

I have been informed about the purpose, procedures, possible benefits, and risks of this research study. I have read (or the Investigator obtaining my consent has read to me) this form, and I have received a copy of it. I have had the opportunity to ask questions and to discuss the study with Elena St. Amour. My questions have been answered to my satisfaction. I have been told that I can ask other questions any time. I voluntarily agree to participate in this study. I am free to withdraw from this study at any time without penalty and without the need to justify my decision. The withdrawal will not in any way affect any benefits to which I am otherwise entitled. I agree to cooperate with the principal investigator and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

Type Initials in Text Box

Initialing, I understand the risks and benefits of this research and agree to participate.

Below, I have indicated my decision about being re-contacted for related studies in the future by placing an "X" next to my choice:

☐ Yes, please contact me about related studies.

☐ No, please do NOT contact me about related studies.

Participant: Please type your full name in the text box, choose today's date, and digitally sign if you choose to volunteer.

Enter Full Name of Participant	
Full Name of Participant	Date

By electronically signing this consent form, you indicate that you acknowledge and understand the terms of the Informed Consent and are voluntarily choosing to participate in this research. Upon signing the document will be locked and cannot be modified unless your signature is deleted.

This form, by law to protect PII, is retained in an IL4 level database for 3 years and then destroyed.

To sign: Insert your Personal Identity Verification card into the reader; click the X below to sign.

X _____

Signature of Participant

Investigator Obtaining Participant's Consent

Electronic Institutional Review Board (eIRB) Interface Usability Evaluation

I have fully explained this study, to the best of my ability, to (Enter Participant's Full Name), hereinafter referred to as the Participant. As a representative of this study, I have explained the purpose, the procedures, the possible benefits, and risks that are involved in this research study. I have answered the Participant's questions to his/her satisfaction before requesting the signature of the Participant. I confirm that the Participant has not been coerced into giving consent, and the consent has been given freely and voluntarily. There are no blanks in this document. A copy of the signed Informed Consent forms (Participant's & Principal Investigator Obtaining Consent) have been provided to the Participant.

Full Name of Investigator Obtaining Consent

Printed name of Principal Investigator Obtaining Consent

X _____

Investigator Obtaining Participant's Consent

Date Time

B System Usability Scale

1. I think that I would like to use this system frequently.

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

2. I found the system unnecessarily complex.

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

3. I thought the system was easy to use.

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

4. I think that I would need the support of a technical person to be able to use this system.

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

5. I found the various functions in this system were well-integrated.

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

6. I thought there was too much inconsistency in this system.

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

7. I would imagine that most people would learn to use this system very quickly.

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

8. I found the system very cumbersome to use.

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

9. I felt very confident using the system.

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

10. I needed to learn a lot of things before I could get going with this system.

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

C Follow-Up Questionnaire

1. **How satisfied are you with the ease of registering a protocol on the "Registration Page" of the eIRB interface?**

☐Very dissatisfied

☐Somewhat dissatisfied

☐Neither dissatisfied nor satisfied

☐Somewhat satisfied

☐Very satisfied

2. **How easy would it be for you to fill out a protocol submission form using the "Submission Form Fill" screen of the eIRB interface without any instructions?**

☐Very difficult

☐Somewhat difficult

☐Neither difficult nor easy

☐Somewhat easy

☐Very easy

3. **How easy would it be for you to upload the necessary files for final protocol submission on the "Submit Protocol for IRB Review" screen of the eIRB interface?**

☐Very difficult

☐Somewhat difficult

☐Neither difficult nor easy

☐Somewhat easy

☐Very easy

4. **Compared to the current process for making a protocol submission to the IRB for review, how much easier did you find it to submit a protocol for IRB review with the eIRB interface?**

☐Much harder

☐Somewhat harder

☐Neither harder nor easier

☐Somewhat easier

☐Much easier

☐Not applicable/Have not previously submitted to the IRB

5. **Do you have any questions, comments, or suggestions about the electronic IRB interface?**

D Participant Procedure

Before starting, navigate to "IRB PI Submission & Workflow" in Microsoft Power Apps (IRB PI Submission & Workflow MBA - Power Apps)

Task 1: Register your research protocol with the local (WJHTC) IRB/Registration Page

1. Where it says "Title of Research Project", type "FAA System Assessment 03/17".
    a. Notice that you receive an error message indicating that you have used an invalid character. Can you demonstrate how you would go about correcting this?

    Researcher prompt: Ask participants share their insights on next steps in the overall task and interface navigation.
2. Under "Name of Principal Investigator (PI)", where it says "First Name", type your first name.
3. Under "Name of Principal Investigator (PI)", where it says "Last Name", type your last name.
4. Your email address should automatically appear in the "FAA email" box.
    a. If your FAA email does not appear in the "FAA email" box, type your FAA email address.
5. When all entries have been completed, click the "CLICK HERE" button to establish your PI folder, which will be accessible via the email address that you entered.
6. Please navigate to your email and follow the instructions to access your PI folder.
7. Return to the registration page when you believe you are finished.

    Researcher prompt: Ask participants share their insights on next steps in the overall task and interface navigation.
8. Click the "Submission Form Fill" button.

Task 2: IRB Submission Form Fill Page

9. On the "Submission Form Fill" screen, select the "Project Title" dropdown.
10. Select the title that you inputted on the initial registration page.
    a. The "Principal Investigator", "Position", "Department", and "Phone" fields should be filled in automatically. If any of that information is incorrect or left blank, input the correct information.

11. Input the following information into the remaining fields:
    a. In the “CoPI” field, input “John Smith”.
    b. In the “CoPI Position” field, input “Research Engineer”.
    c. In the “CoPI Department” field, input “ANG-123”.
    d. In the “CoPI Phone” field, input “123-456-7890"
    e. In the “Collaborating Investigators” and “Consultants” fields, make no edits.
    f. In the “Contractor” field, input “Jane Doe”.
    g. In the “Sponsoring Organization” field, make no edits.
    h. In the “Organization Conducting Research field, input “William J. Hughes Technical Center”
12. Under “Proposed Start Date”, select May 5, 2025.
13. After selecting May 5, 2025, select “Ok”.
14. Under “Proposed End Date”, select June 9, 2025.
15. After selecting June 9, 2025, select “Ok”.
16. Make the following selections for each of the following yes/no dropdowns:
    a. Under “Other HHS IRB Approved”, select “No”.
    b. Under “Children”, select “No”.
    c. Under “Pregnant Women”, select “No”.
    d. Under “Prisoners”, select “No”.
    e. Under “Impairment: Cognitive or Physical”, select “No”.
    f. Under “Individuals who report to the organization conducting the work”, select “Yes”.
    g. Under “Individuals who report to the sponsoring organization”, select “Yes”.
    h. Under “Projected Number of Volunteers”, input 15.
18. Electronically sign the document by holding down the left mouse button and writing your signature.

    Researcher prompt: Ask participants share their insights on next steps in the overall task and interface navigation.

a. Click the pencil icon on the bottom right-hand side of the signature panel to change the color and opacity of your signature

b. Click the four lines icon on the right-hand side of the signature panel to change the thickness of your signature and eraser area

c. Click the X icon on the left-hand side of the signature panel to fully delete the signature that you have typed

d. Click the eraser icon on the left-hand side of the signature panel to erase parts of your signature

e. The date and time of signature will appear once edits to this form have been saved.

19. In the "Problem Statement" text box, type the following Problem Statement: "This is a problem statement."

20. In the "Volunteers" text box, type the following Volunteer information: "This is volunteer information."

21. In the "Materials" text box, type the following Materials information: "These are the materials being used in this study."

22. In the "Procedure" text box, type the following Procedure: "This is the procedure."

23. In the "Results/Data Management" text box, type the following Results/Data Management strategy: "These are the final results, and this is the data management strategy."

    a. For steps 19-23, text may also be pasted into each text box. Speech-to-text may also be used to input information.

    b. To paste text, you would copy the desired text, then right-click the desired text box and click "Paste".

    c. To enable speech-to-text, click the Windows key + H on your device.

        i. Then click the microphone button that pops up.

        ii. When you are finished speaking, click the microphone button again.

        iii. Close the microphone window.

    d. To save edits made to this form, click "Save Edits to Form".

    e. Upon saving any edits made to your form, the form will be available in your PI folder as a Microsoft Word document and as a PDF.

24. To reset the entire form to its initial default state, click "Reset Form to defaults".

Researcher prompt: Ask participants share their insights on next steps in the overall task and interface navigation.

25. When any desired edits have been saved, to your IRB application form, click "Submission for IRB Review".

    Researcher prompt: Ask participants share their insights on next steps in the overall task and interface navigation.

Task 3: Submit Protocol for IRB Review

26. Click the "Submit New Project" dropdown and select your project title.
    a. The submission form generated after saving your edits on the "IRB Submission Form Fill" screen should appear automatically in the "Submission Form" box.
27. Next, you will upload your informed consent paperwork.

    For steps 27 – 32 Researcher prompt: Ask participants share their insights on next steps in the overall task and interface navigation.

28. For context: to fill out the Informed Consent paperwork, you will need to access your PI folder, which is described in Step 5.
29. Navigate back to your PI folder, which you opened as part of step 5.
30. Within your PI folder, click "Add Shortcut to OneDrive"
31. Click "Upload file" under the "Informed Consent Form" section to upload the completed "Participant's Informed Consent" document from your PI folder once it is added to your OneDrive.
32. Within your OneDrive, search for the folder that matches the title of your project.
    a. The "Informed Consent" document exists within the "Informed Consent Templates Folder".
    b. Left-click to select the "Informed Consent" document within the "Informed Consent Templates Folder".
    c. Click "Open"
33. When all necessary files are uploaded, which in this case are just the Submission Form and Informed Consent document, click "Submit Protocol for Review".
    a. For context: any questionnaires, surveys, or other additional documents that you wish to submit alongside your protocol must be created in or uploaded to your PI folder. Only the submission form and informed consent document are required for submission.

34. Following the submission of your protocol for review, you will receive an email thanking you for your submission. No action or response to that email is necessary.

Task 4: Submitting a Submission Revision

35. To make a revision to your protocol after it has already been submitted, click on the "Submit Revision" dropdown arrow.

36. Select the title of the protocol that you wish to make a revision to.

    a. To make changes to the submission form, navigate back to the submission form fill screen.

       Researcher prompt: Ask participants share their insights on next steps in the overall task and interface navigation.

    b. On the submission form fill screen, select the project title of the protocol that you wish to make a revision to.

    c. In this case, we will edit the start and end dates for your initial submission.

       i. Under "Proposed Start Date", select May 12, 2025.

       ii. After selecting May 12, 2025, select "Ok".

       iii. Under "Proposed End Date", select June 16, 2025.

       iv. After selecting June 16, 2025, select "Ok".

       v. To save edits made to this form, click "Save Edits to Form".

    d. Navigate back to the Submit Protocol for IRB Review screen.

    e. You are now going to make a revision to the informed consent document you previously uploaded, click the X icon to the right of the file name to remove.

       Researcher prompt: Ask participants share their insights on next steps in the overall task and interface navigation.

       i. In this case, click the X icon to the right of the file uploaded under "Informed Consent Form".

       ii. Click "Upload file" under the "Informed Consent Form" section to upload a revised informed consent form.

       iii. Within your OneDrive, search for the folder that matches the title of your project.

       iv. Navigate to the Informed Consent Templates folder.

v. Left-click to select the “Investigator Obtaining Participant’s Informed Consent” document within the “Informed Consent Templates Folder”.

vi. Click “Open”.

37. When you have made the revisions, click “Submit Protocol for Review”.

38. Following the re-submission of your protocol for review, you will receive an email thanking you for your submission. No action or response to that email is necessary.

E Participant Comments

Key
Blue - Participant Likes
Orange - Interface Changes
Yellow - Confusion & Question's

Navigation		
Registration Page	**Submission Form Fill Page**	**Submission for IRB Review Page**
Participant didn't realize that the "Registration page" was the home page screen. Participant tried to click the edge back arrow, said that there should be a back button or a "home page"	Participant was unsure if they could navigate back to the Registration page after on the Submission Form Fill screen. Participant said that we should add a back button.	
Participant stated that the "submission form fill" button should indicate that it's the next or second step.	Participant suggested possibly renaming registration page button as "Home screen"	
Participant stated that people may not know that the landing screen is the registration page, they might not associate the "registration page" button with the landing screen. More indication on the landing screen should be made to show that it is a registration page.	Participant stated that there should be more clarity on the flow of the webpage and the steps.	
Participant stated that there should be instructions telling the user where to go next after checking their email		
Participant stated that the "Submission for IRB Review" button should not be on the landing screen. For example, there may be a scenario in which the user might want to go to the "Submission for IRB review page first.		
Participant was unsure of how to get back to the PI folder after leaving.		
Participant wanted clarification on the difference between the "Submission Form Fill" and "Submission for IRB Review". Said they would be confused on the difference between each button.		
Participant started looking at the bottom of the page buttons. Said that they might use the email/PI folder to fill out documents before ever coming back to the form fill screen.		
Participant said they wouldn't know to come back to the landing screen page after viewing the initial email, the instructions		

did not say anything about coming back to that page. Participant said they would not have known to navigate to their email for their PI folder themselves without instruction. Said that it was not intuitive that users would need to navigate to email.		
Participant hit the back button on the browser, and it caused a white-out issue on the screen. Participant then skipped to "submission for IRB review" page. Another participant incorrectly thought they would click on the "submission for IRB review" button next. Stated that should be a clear indicator of what the next step is. Step 1, step 2, etc.		

Functionality		
Registration Page	**Submission Form Fill Page**	**Submission for IRB Review Page**
Participant liked the use of the color coding and the ease of use when typing into the "First Name/Last Name Boxes"	Participant thought the width of signature feature was cool but would never use	Participant said there should be a pop up, confirming that they have made a submission and that they will receive an email confirmation (**3**).
Participant liked the search bar that came up to find user email	Participant suggested having a confirmation message on submission form fill page, such as: ”Your edits were successfully saved” because the participant said they might have thought their edits were erased.	Participant thought that the form fill button is on too many pages, should be hidden, because on the “submission” screen it made the user feel like they were forgetting to do something and still needed to do something. Participant said having the registration button on each page is useful because [its used for] navigation, but the form fill button is a task you are doing. [Participant thought it was confusing to have a navigation button next to a task button]
Participant likes that the system will automatically keep required documents/information. Participant said this is better than keeping paper copies or folders on their own computer	Participant stated that someone wouldn’t know to go to the “Submission for IRB review” from the form fill screen without clicking on it. Participant wouldn’t realize there was a next step. It was suggested that there be a pop up moving you forward to the next screen (**2**)	Participant stated that there should be a note somewhere on the “Submit Protocol for IRB review” page so participant knows what document types they can/cannot upload.
Participant believed that there should be a confirmation message after selecting "Click Here" (**4**)	Participant thought that users shouldn’t have to backspace and get rid of “N/A”. Participant stated that it would be better to just have the N/A go away once clicked on or start with a blank field.	Participant suggested having emails sent from a general email address, not a specific person
Participant wished that there was a [pop-up] message on this screen with direction saying “Once completed please navigate to form fill screen”	When the participant first came to the page, they didn't realize that all of the information was field labels. To the participant, it just looked like decorative words were floating around. The participant was not sure that a user would know to select drop down first. The participant suggested having project title with pull down, without the field labels showing, and then once selected the field labels can appear or having field labels with white blank field boxes (**2**)	After submitting, participant said there should be some directions asking the user if they want to submit another protocol. Another participant said there should be something notifying the user that “You are about to submit your final protocol” then let the user know where to move onto next, because after submitting you stay on the same page.

Participant suggested that the "Submission for IRB" review button should be grayed out until the participant is ready for that step, since, at this point, the participant is only ready for the "Submission Form Fill" section.	Participant asked why the signature is showing double. Said that we should get rid of mirrored part of signature.	Participant accessed the IRB PI folders and said that other users should not be able to access this.
Participant suggested to get rid of dropdown arrow on email search bar.	Participant said we should get rid of "Date Signed" section because it looks like they needed to add in the date. (**3**)	Participant recommended maybe building the rest of the documents in the PI folder into the Power Apps screens.
Participant stated that there should be two buttons. One being for "returning users" for people who have already registered and another button for people who are newly registering a protocol.	Participant didn't think we needed to have the thickness and color options because it's not necessary (**2**) Another participant said at this point people wouldn't use these options because they are just wanting to get this off their desk.	Participant said that they would probably use the document in the PI folder to make revisions because that is the method they are used to using for making edits. But also said that overall, both methods are fairly easy to use.
Look into possibility of registering protocol via cellphone or iPad.	At the Results/Data Management section - Participant stated that there should be something helping the participant to know that they need to scroll down. The participant suggested that maybe there should be a smaller box, and then the box can expand so they can see the whole text, which would allow more space for the user to see that they need to scroll down.	Participant stated that there should be something that tells user they can only upload one document per box.
User should be automatically advanced to the IRB Submission form fill or next step (**2**). Another participant said "Should not save, and land on the same screen."	Participant suggested that following pressing the "Reset Form to Defaults" button there should be an "Are you sure?" prompt (2)	Participant suggested changing "Additional Information document" to "File 1, File 2, File 3, File 4" because additional information is unclear to them and would further clarify for the user that they can only upload 1 file per box.
Participant stated that the "Submission Form Fill" and "Submission for IRB Review" buttons should be hidden.	After clicking save edits to form - Participant said they would have liked some feedback (3); said they wouldn't know the above information about the form being saved into the PI folder. Participant suggested maybe a popup with a link to their folder Another participant said there should be a prompt saying "saved in folder" or a pop up. Participant assumed that they would receive an email at this point (2) - Another participant said maybe have an email go to user, "We've received your initial document, here's where you need to go next"	Participant commented on the follow direction on the interface and stated that instead of having two dropdowns, these options should be a radio button selection. *To make a revision to your protocol after it has already been submitted, click on the "Submit Revision" dropdown arrow.*

Participant stated that the "Submission Form Fill" and "Submission for IRB Review" buttons should be hidden.	Participant recommended that we use PIV to sign. (**4**)	Participant said that the steps for syncing to one drive are complicated (**8**)
Participant wanted clarification – If they have 5 separate protocols, they will have 5 separate folders.	Participant asked if they made changes before moving forward, if they would receive an error message if they did not save. Participant said if this was not capable in Power Apps to add, there should be a message in red at the top.	Participant uploaded their own study informed consent documents (**3**). Participant asked if there's something on the eIRB side that needs to be accepted?
	Participant noted there should be a question mark toggle to include a bit more information about the proposed end date. Participant asked "what if the user does not have a specific end date at the time they are filling this out?" Participant suggested maybe having a question mark that the user can hover over.	Participant tried to click on the document in the "Submission Form" and it opened up an error screen page in a new window (**5**) Participant said that they would like the old file to still be present, so they can see that they are making changes and that a new document is uploaded.
	Participant wasn't sure why there were two signature boxes and tried to initially sign on the right side before signing on the left side. Participant recommended more indication to the side of the box that needs to be signed and suggested that maybe the left side of the box be outlined/highlighted.	Participant was confused about the difference between "Submit New Project" and "Submit Revision" - Participant had to clarify on this step if the idea was to choose one option or the other.
	Participant stated that on the "proposed start date" selection, there should be an error message if the start date is a previous date.	Before being walked through the syncing to one drive steps - Participant assumed they would download the document from their PI folder, and re-upload.
	Participant stated that there should be a specific instruction about the signature block that the user needs to sign. Participant thought that the box was part of the above boxes, and more information needed to be added. Participant suggested that there should be a label, the signature block should be a different size, and that the signature box should be a rectangle instead of a square. Participant also recommended maybe having "By typing your name here" as a signature	On the form fill screen, participant made edits and did not click save. Participant went to the submission screen and then back to the form fill screen, and the edits were still there.
	Participant suggested that on this screen, any of the required information needs to have a red *	Participant Questions: If anything were to happen, i.e. if chair goes to a different organization, how hard is it to change the chair's name in

		all the email popups? Is it possible to get an IRB interview address?
	Participant suggested that "Submission for IRB review" button needs to be hidden until user needs to move on.	
	Participant suggested that "Registration page" button needs to say "Back to registration page"	
	Participant stated that the title of the page needs to match the name of the button on the registration page	
	Participant said that we should label the signature box and asked if people could type their name as a signature (**2**)	
	Participant was unsure if it would be helpful to have the form re-populate with information after "Save edits to form" is clicked, instead of going back to a blank page. Participant said they could see pros and cons of both. Participant said that they would assume that someone who is saving edits to the form is going to step away and not come back to the form.	
	Participant asked if there was a character limit on the text box.	
	Participant did not think the eraser symbol was an intuitive signature, also did not think the option to change pen color was needed but it's not hurtful	
	Participant wanted to know if any text pasted into the document would take the same format, can bullet points be added?	
	Participant wanted to know when the "Reset forms to default" would be used. Recommended that there should be an information icon to have more information about this button.	
	Participant said that will the project title selected; the page looks more straightforward. But without the project title selected the screen is more confusing.	

Design Aesthetic		
Registration Page	**Submission Form Fill Page**	**Submission for IRB Review Page**
"Colors seem fine" Participant liked that the form options turn green once filled.	Participant thought the amount of space to sign was great.	Participant suggested that there be "One line" kind of like a control panel, that would house the buttons. Participant recommended having a "line" of buttons at the top of the screen with the same blue color as the buttons already there. This line would have all of the available pages that one would need to navigate through.
Participant liked the use of the color coding and the ease of use when typing into the "First Name/Last Name Boxes" and clearing this information (**2**)	Participant liked that the pen feature is highlighted when selected	Participant recommended getting rid of picture of plane on Submit Protocol for IRB Review.
Participant said they liked the "Submission Form Fill" and "Submission for IRB review" buttons being on the bottom left, the positioning makes the button placement clear.	Participant recommended that the buttons on the "IRB Submission form fill" screen be different. Stated that the "IRB review just feels different than like save edits to form button" Participant also recommended that the color be changed to maybe a grey or lighter blue. But in general, it is not confusing.	
Participant liked that the fields are highlighted when you click into them.	Participant did not like that the words on the "IRB Submission Form Fill" screen were free floating, said that they kind of felt displaced and kind of dizzying.	
Participant liked the use of the color coding and the ease of use when typing into the "First Name/Last Name Boxes"	Participant stated that the form fill screen looks really chaotic, and that the text labels for a field all need to be on the left, the boxes should be the same sizes and lined up	
The participant stated that purple on the text boxes felt like too much color and didn't think that the purple was necessary but doesn't hurt anything.	Participant disliked that when "Reset form to defaults" is clicked that the text boxes disappear. Participant stated that the text boxes should still be there, even if just blank.	
Participant thought that the buttons on the bottom of the page should have a bit more cushion, raised up a bit more because they look a bit smashed.		
Participant suggested to change the color of the "click here box" to		

make it more apparent that it is a button. (**3**)		
Participant said that the top of the landing screen seems a little busy, maybe remove one of the FAA logos. Another participant noted there is a lot going on in the header, might want to get rid of the blue background banner at the top to reduce the noise. Another participant stated that the additional information at the top needs to be moved to the bottom, get rid of the globe.		
Participant said the “form fill” and “IRB review" buttons could be made more obvious, either bigger or more centralized.		
Participant noted that we should not make form fields yellow or green, since yellow typically means warning. Participant suggested possibly a light grey or blue.		
Participant clicked on the CFR and opened up a new tab. Noted that maybe these links should be moved to the bottom.		
Participant stated that the contrast between the green text and the black text is stark.		
Participant said that we should take away the yellow on the error message, and just make the text red on the error message.		

Instruction & Wording		
Landing Screen	**Submission Form Fill**	**Submission for IRB Review**
Participant commented on the initial registration email - Participant said the email contained a good amount of information, not too much or too little.	Participant commented on the "Materials" section - This section has clearer instructions. This at least says “Describes”	Participant suggested that the “Thank you for your submission” email subject line should be something a little more specific, it should say something about the IRB.
Participant commented on the initial registration email - Participant liked where the “click here” was placed in the email.	Participant commented that the instructions on the "Procedure" section is great and that the same type of language needs to be used in the other boxes as well.	Participant commented on making a submission revision - Participant said there should be some direction, because it is not intuitive to go back to the form fill screen.
		Participant stated that users should receive an email that notes that a revision was submitted. “There was a revision submitted for [Insert document name]”
Participant commented on the initial registration email - The “click here” is pretty early in the document, might move that statement later so participants at least read through most of the directions before moving onto opening the PI folder.	Participant pointed out that “Whose ability to self-determine maybe comprised "needs to be changed to “may be”	Participant wanted to confirm process after the final submission: “After you complete the submission, will the participant hear back from the chair?
Participant commented on the initial registration email - Participant would like a different email subject something with “IRB” in the name.	Participant thought that there should be instructions next to the problem statement field label (**4**) Participant recommended: “Problem Statement: Enter your problem statement below...”	
Participant commented on the initial registration email - All of the information in the email was clear. However, there was a combination of bullets/numbers together which made the email look busy. The numbers in the email should be replaced with solid bullets.	Participant commented on the "Volunteers" section - Participant doesn’t think that the instructions are really instructions. They look like guidelines. There should clearly be “Please enter ...” (**2**) Another participant recommended: Need to add instruction “Describe volunteers in text below”	
Participant commented on the initial registration email - Participant said that there should be an extra space after the sentence “If any of the above documents or folders to not immediately appear...”	Participant said it should say “Co-PI” because it was unclear what that was.	
Participant stated that text in the boxes on the registration page should be changed to “Enter name of Principal Investigator” etc.	Participant commented that “Volunteer” and all other titles should be bolded.	

Participant stated that if there is a specific format that we want users to follow then that should be noted as one of the directions on the landing screen, which would set user up for success by telling them, "Enter the title of your research project in X format, avoid using special characters.	Participant was unclear on if they should just type like the number of underrepresented participants they are using, or a simple yes/no? Unclear on the type of information that is needed because of the lack of instructions. (**4**) Another participant said: It was unclear if PI would need to make an effort to include underrepresented groups or just document if they are part of the group and just need to include demographic information.	
Participant said that the first line of email seems unclear. They thought that the "registration" was the whole process, not just titling your research project and adding your email.	Participant commented on this statement, saying unsure if this will need to be changed in the current climate. "An effort must be shown to include underrepresented groups"	
Participant commented about the initial registration email - Not sure how intuitive this statement is for the user, not sure if user would know what to do "Upon completion of the necessary documents, submit them on the Submit Protocol for IRB Review screen."	Participant said that this statement should be changed: "The IRB reviews the level of risk" instead of "for level of risk"	
	Participant said that not everyone might not know what beneficence is if they haven't done any IRB or CITI training (**2**), so there should be a link to some more information. Another participant said - "Information with beneficence in mind" - Beneficence needs to be changed, plain language needs to be used.	
	Participant commented that in listing the ERAM, STARS, ATOP, Aircraft simulator information, there should be consistency in the word formatting. This should use the parenthesis and (e.g.,)	
	Participant commented that "Save edits to form" button should be renamed to "Save for later "	
	Participant was unsure how much information is needed in text boxes. Should they be categorized or should every piece of material be listed?	
	Participant said that this sentence should be fixed and cleaned up a bit	

	to be clearer. Participant said this should possibly be 2 sentences. *"Provide a description of the scenario & associate volunteer activities described in sufficient detail that someone unfamiliar with your procedure can replicate it."*	
	Participant commented that the "Results/Data Management" text should be changed, this information should be on the same line. (Not “The Data Management Plan”) Our concern is how the data...	
	Participant commented that the copy/paste and speech to text options should be listed as part of the directions at the top where it says “Please complete the form providing information...”	
	Participant was unsure of how specific they needed to be about the department. Participant just had ANG on their form fill.	
	Participant asked: "On top part of form fill screen, if you put in information for a PI, are you as a CoPI and the PI both getting emails or being contacted? Or what does it mean when you put in both people's contact info?" Participant said there should be a question mark icon at least with a little help, or more context/information.	
	Participant was unsure what “The Data Management Plan” was (**2**). Participant said they do not recall having to use/create a separate document for data management.	
	Participant wanted to know what the “HHS IRB” was.	
	Participant asked: If PI doesn’t have a problem statement, what else can they include?	
	Participant said this should be worded differently: Results/Data Management (Not "The Data Management Plan") Participant said that it should possibly be a separate point at the end: “Not the data management plan”	

User Experience		
Landing Screen	**Submission Form Fill**	**Submission for IRB Review**
Participant thought the landing screen was pretty clear and easy to understand (**2**)	Windows + H Key - Participant said they liked this feature (**5**).	Participant liked that when you hover over the "upload file" the line gets darker, indicating you are going to click on that item.
Participant recommended that training should be added onto either the landing screen or another part of this page. Link should be added to the CITI if the IRB wants to get more people looking at their material.	Participant stated that the form fill screen is self-explanatory.	Participant said that overall they liked this process because the old process was a bit difficult to format. In the past, they would have had to include all of your documents into a specific template.
	Participant enjoyed Windows + H Key shortcut, but said it was not intuitive, participant would not have known to use that.	Participant liked the * on the required forms
	Participant said "oh nice!" indicating that they liked that the information automatically filled.	Participant said overall they are excited to use this form in the future for IRB submissions.
	Participant said that they thought this whole process was a lot more seamless than the previous process and more straightforward.	Participant mentioned exempt/expedited - it was explained that the chair would be deciding this for the PI. Participant said that this would be useful because there was always some confusion on that.
	Participant said they liked the "N/A" in the auto-filled boxes, instead of it being blank	Participant stated interface is a "nice application" because in the past with filling out the forms, formatting was a challenge. Also stated that uploading the documents on the interface is a lot simpler.
	Participant liked that this interface is user friendly.	After Elena provided an overview of this screen, participant said it was intuitive and easy to understand
	Participant liked the idea of being able to copy/paste text into the text's boxes. Said "Oh nice"	Participant said that they were not familiar with OneDrive so they thought some type of "help" would be useful.
	Participant commented that the signature functionality could be a little better and the signature is blurry, but not blurry on the document.	Participant said there should be some type of training videos on how to do OneDrive steps because it is not intuitive (**6**). Participant did not think they would know how to complete OneDrive sync steps (5). Participant said they would have gone back to the initial email to look for instruction. Another participant said these steps should be in the email (**2**) Another participant said that they were not familiar with OneDrive so

		they thought some type of "help" would be useful or that there would be instruction on the "Submit Protocol" screen saying, "upload from OneDrive..." Another participant said - Training might be useful. Not necessarily with a lot of detail, but an overview, but maybe like a YouTube video with timestamp tags of where specific tasks are being completed for the user to reference.
	Participant said they hate signing things with their mouse.	Participant wanted to know if PDF, Word Docs, images, etc., could be uploaded. Participant stated that they often would get different qualities of submissions, so it would be helpful to mention to users that they should take advantage of the PI folder for organization.
		Participant wanted to know what type of "additional information" would be needed to upload and stated that there should also be an information icon with examples of things users might want to upload. Maybe list best practices (like having your submissions in your PI folder).