



CCDC DAC-TR-2020-064
August 2020

Development and Evaluation of Software for Obtaining Informed Consent

**by Christopher Garneau, Theresa Straut, Jennifer Biladeau, and
Kristin E. Schaefer**

DESTRUCTION NOTICE

Destroy by any method that will prevent disclosure of contents or reconstruction of the document.

DISCLAIMER

The findings in this report are not to be construed as an official Department of the Army position unless so specified by other official documentation.

WARNING

Information and data contained in this document are based on the input available at the time of preparation.

TRADE NAMES

The use of trade names in this report does not constitute an official endorsement or approval of the use of such commercial hardware or software. The report may not be cited for purposes of advertisement.



CCDC DAC-TR-2020-064
August 2020

Development and Evaluation of Software for Obtaining Informed Consent

by Christopher Garneau
CCDC Data & Analysis Center

Theresa Straut, Jennifer Biladeau, and Kristin E. Schaefer
CCDC Army Research Laboratory

REPORT DOCUMENTATION PAGE			<i>Form Approved</i> OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.				
1. REPORT DATE August 2020		2. REPORT TYPE Technical Report		3. DATES COVERED (From - To) 1 Oct 2017–1 May 2020
4. TITLE AND SUBTITLE Development and Evaluation of Software for Obtaining Informed Consent			5a. CONTRACT NUMBER	
			5b. GRANT NUMBER	
			5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Christopher Garneau, Theresa Straut, Jennifer Biladeau, and Kristin E. Schaefer			5d. PROJECT NUMBER	
			5e. TASK NUMBER	
			5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Director U.S. Army CCDC Data & Analysis Center 6896 Mauchly Street, Aberdeen Proving Ground, MD U.S. Army CCDC Army Research Laboratory, Aberdeen Proving Ground, MD			8. PERFORMING ORGANIZATION REPORT NUMBER CCDC DAC-TR-2020-064	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) CCDC Army Research Laboratory Aberdeen Proving Ground, MD			10. SPONSOR/MONITOR'S ACRONYM(S) CCDC ARL	
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT DISTRIBUTION STATEMENT A. Approved for public release; distribution is unlimited.				
13. SUPPLEMENTARY NOTES				
14. ABSTRACT Obtaining informed consent (IC) in studies under Institutional Review Board (IRB) oversight is a requirement per 32 CFR 219.116. Traditional means of obtaining IC via paper forms can be inconvenient for field studies or where travel is required and are prone to various IC form discrepancies. The U.S. Army Combat Capabilities Development Command (CCDC) Army Research Laboratory (ARL) Human Research Protection Program (HRPP) is developing, evaluating, and implementing an IC form system that addresses the challenges inherent in traditional methods via a software application called Informed Consent + (IC+). While commercial off-the-shelf (COTS), open-source, and proprietary electronic IC applications already exist and have been investigated for use in clinical and research settings, these solutions are unsatisfactory for several reasons: 1) CCDC Army Research Laboratory studies are frequently conducted in environments without internet access, 2) extant applications do not meet all requirements of the ARL HRPP, and 3) cost and information-assurance requirements make installation of COTS enterprise software prohibitive. The purpose of this report is to review the development of the IC+ app—including requirements, features, and screenshots—and discuss the results of evaluation efforts conducted with researchers to assess its performance, usability, and benefits or limitations.				
15. SUBJECT TERMS informed consent, electronic forms, process improvement, human subjects research, mobile applications				
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT SAME AS REPORT	18. NUMBER OF PAGES 45
a. REPORT UNCLASSIFIED	b. ABSTRACT UNCLASSIFIED	c. THIS PAGE UNCLASSIFIED		
				19b. TELEPHONE NUMBER (include area code) 410-278-5814

Table of Contents

List of Figures	iv
List of Tables.....	v
Executive Summary	vi
1. INTRODUCTION AND REQUIREMENTS	1
2. OVERVIEW OF FUNCTIONALITY	3
3. USABILITY EVALUATIONS.....	9
3.1 2018 Evaluation.....	9
3.2 Winter 2020 Evaluation, Phase I.....	11
3.3 Winter 2020 Evaluation, Phase II.....	12
4. CONCLUSIONS AND FUTURE WORK.....	14
5. REFERENCES AND DOCUMENTS	15
Appendix A – List of Acronyms.....	A-1
Appendix B – Informed Consent + (IC+) Prototype (v0.1).....	B-1
Appendix C – Informed Consent + (IC+) v0.6 and v0.8 from Usability Evaluations	C-1
Appendix D – Distribution List	D-1

List of Figures

Figure 1.	Main view in IC+ upon starting IC+ for the first time	3
Figure 2.	Administration view showing a study having been configured but without any participants having been added	4
Figure 3	Main view in IC+ locked and ready for participants to consent.....	5
Figure 4.	Consent form for the study as displayed in IC+ for participant review	6
Figure 5.	Signature view in IC+ after participant reviews consent form and chooses to participate	7
Figure 6.	Administration view showing a study having been configured and two participants having consented to participate in the study	8
Figure 7.	Benchmark normalized SUS scores	12
Figure B-1.	Researcher view for adding new studies or monitoring participants of an ongoing or concluded study.....	B-2
Figure B-2.	To create a new study, users will need to add the study title so they are able to differentiate between their studies on the app; the PI name should be the full name of the PI. It is used by the app to add a printed name to the electronic signature	B-3
Figure B-3.	Consent form view for participants, the approved PDF from the IRB office. Participants can scroll through multiple pages by selecting the forward or back arrows, and agree or decline participation. If they agree to participation, a signature window opens.	B-4
Figure B-4.	Each participant adds their full name (as it provides a printed name to the signature block) and may provide an email address. An email address is needed to receive an electronic version of the signed IC form.....	B-5
Figure C-1.	Home screen (unlocked).....	C-2
Figure C-2.	Home screen (locked for administration of informed consent [IC])	C-3
Figure C-3.	Participant input of name and email address	C-4
Figure C-4.	Participant view of administrator-uploaded IC form.....	C-5
Figure C-5.	Participant signature screen	C-6
Figure C-6.	Study administration screen for research administrator	C-7
Figure C-7.	Initial home screen (unlocked)	C-8
Figure C-8.	Sample home screen (locked for administration of IC).....	C-9
Figure C-9.	Participant signature screen	C-10
Figure C-10.	Sample study administration screen for research administrator.....	C-11

List of Tables

Table 1.	Responses from the Seven Potential Users of the System for Ease of Use for the Fall 2018 Evaluation.....	10
Table 2.	Winter 2020 Phase I Ease of Use Results	11

Executive Summary

The U.S. Army Combat Capabilities Development Command (CCDC) Army Research Laboratory (ARL) Human Research Protection Program (HRPP) is developing, evaluating, and implementing an electronic system for obtaining informed consent (IC) that addresses challenges inherent in traditional methods via a software application called Informed Consent + (IC+). While commercial off-the-shelf (COTS), open-source, and proprietary electronic IC applications already exist and have been investigated for use in clinical and research settings (e.g., Friedlander et al., 2011; Obeid et al., 2013; Rothwell et al., 2014; U.S. Food and Drug Administration, 2018), these solutions are unsatisfactory for several reasons: 1) CCDC Army Research Laboratory studies are frequently conducted in environments without internet access, 2) extant applications do not meet all requirements of the ARL HRPP, and 3) cost and information assurance requirements make installation of COTS enterprise software prohibitive.

IC+ is being developed to address these challenges and has several main features. The electronic application (app) stores signs and timestamps copies of the latest Institutional Review Board-approved PDF consent form when the participant consents, providing version control with the IC form history. It is designed for use in an offline research environment and does not require internet connectivity; however, it can facilitate sending participants an email with the signed form once connectivity is available. It ensures forms remain secure by requiring administrator account(s) with password protection for access to signed forms. The app is compatible with both tablets and personal computers, though a device with a touch screen is recommended.

The purpose of this report is to review the development of the app—including requirements, features, and screenshots—and discuss the results of evaluation efforts conducted with researchers to assess its performance, usability, and benefits or limitations.

1. INTRODUCTION AND REQUIREMENTS

Obtaining informed consent (IC) in studies under Institutional Review Board (IRB) oversight is a requirement per the code of federal regulations (32 CFR 219.116). Traditional means of obtaining IC via paper forms can be inconvenient for field studies or where travel is required. Additionally, an internal audit conducted from January 2017 to January 2018 revealed that 21 of 25 studies reviewed (84%) had at least one category of IC form discrepancy. Therefore, from its inception, the main goal for creating the Informed Consent + (IC+) electronic application (app) has been twofold: 1) enhance convenience for both researchers and participants, and 2) reduce errors that commonly occur on IC forms.

Digitizing the paper version of the IC form and consent process would make it more convenient for researchers by eliminating the need to carry, track, and secure both unsigned and signed IC forms. It would make the process more convenient for participants by providing them with a digital copy that may be retained on their computer for future reference; traditionally, participants often either do not take or misplace paper IC forms and thus lose access to valuable study information and participant rights contact information. The errors that may be reduced or eliminated by an electronic system include missing or mismatched signatures or dates for participants or researchers, missing optional consent for recording audio, photographs, and so on and the use of an outdated or unapproved IC form.¹

While a solution to the identified challenges would not necessarily require the creation of a new app, the U.S. Army Combat Capabilities Development Command (CCDC) Army Research Laboratory (ARL) Human Research Protection Program (HRPP) staff and development team chose this option in early discussions for the most flexibility in developing a customized strategy. These discussions identified several features required for the new system:

- Signature box for participants to sign with a stylus or their finger
- Signature boxes should be configurable, or have multiple boxes for video and audio consent
- Should allow for the use of an IRB-approved PDF version of the IC form
- Provide a participant with the option to have the signed IC form emailed to them for digital tracking

¹ Further discussion of the benefits and considerations for implementing an electronic IC system have been published by the U.S. Food and Drug Administration (2016).

-
-
- Must be able to be used in an environment without network connectivity; keep signed forms on the tablet, then provide an option to sync or download when internet access is available
 - Must be password protected
 - Signed forms must be locked (not editable) and forms should be automatically timestamped to prevent backdating
 - Track previous versions of an IC form as new versions are approved by the HRPP and uploaded to the app
 - Keep a subject log to provide the ability to generate a report of participant activity
 - The inputs to be tracked in the app include name, signature(s), timestamps, and participant's email
 - Researcher must provide name and signature at the time the participant consents by signing the document
 - The app should be tailored to the needs of researchers who travel or do field studies
 - Provide the ability to zoom in on the PDF form to accommodate different size devices and vision needs

Based on these requirements, a prototype app was developed using Ionic. Ionic is an open-source framework for hybrid mobile app development that uses readily accessible web languages and libraries (i.e., HTML, JavaScript, CSS, and derived frameworks like AngularJS). This framework provides a standardized structure to the source code and a library of user interface elements. It also allows one codebase to be deployed to multiple platforms. For IC+, Windows 10 is the primary target platform (specifically on a Windows tablet) but testing was also conducted on macOS and Android. Deployment on Windows and macOS required use of the Electron framework during development.

2. OVERVIEW OF FUNCTIONALITY

Figures 1 through 6 present screenshots of the various components of IC+ v1.0, the latest version of IC+ as of the writing of this report. IC+ provides both a researcher view for setting up the study and participant view for obtaining consent. Figure 1 depicts the main participant view that displays upon starting IC+ for the first time.

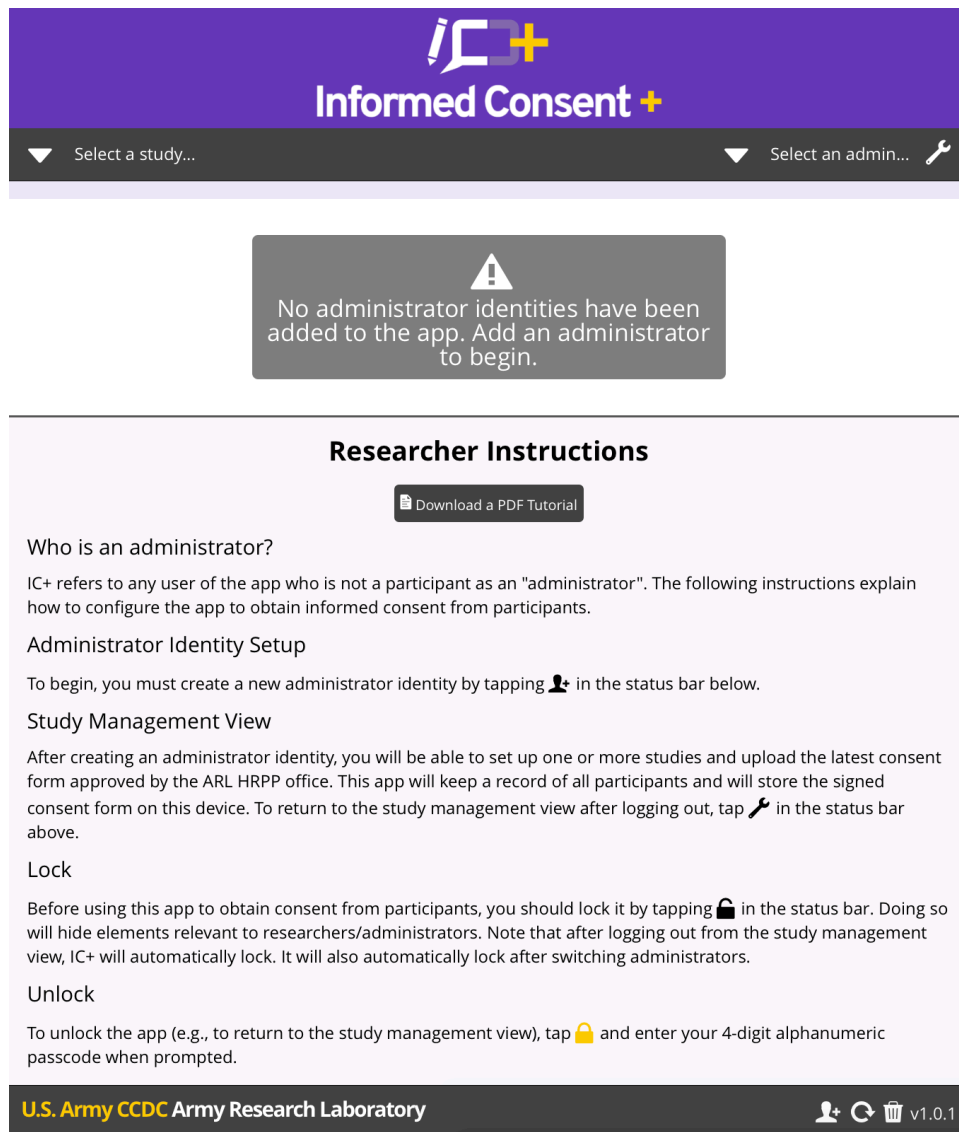


Figure 1. Main view in IC+ upon starting IC+ for the first time

The researcher must first create an account. After entering their full name and a self-selected 4-character alphanumeric password, they are then redirected to the administrator view (Figure 2). Researchers are able to add new studies into the app by selecting the + sign in the menu bar or view previously added studies by selecting one from the drop-down menu. When a researcher selects the option to add a study, they must first select a working title for the study (this short

title identifies the study within the app). Tapping “Import” allows the researcher to upload an IC form in PDF format; all IC forms must be approved by the HRPP before being added to the app. After uploading the IC form, the rest of the study parameters (e.g., principal investigator, project number, etc.) automatically populate from the form but are editable in the app. Researchers are also able to add additional consent options such as audio or video recording (or any other custom options as indicated on the HRPP-approved IC form).

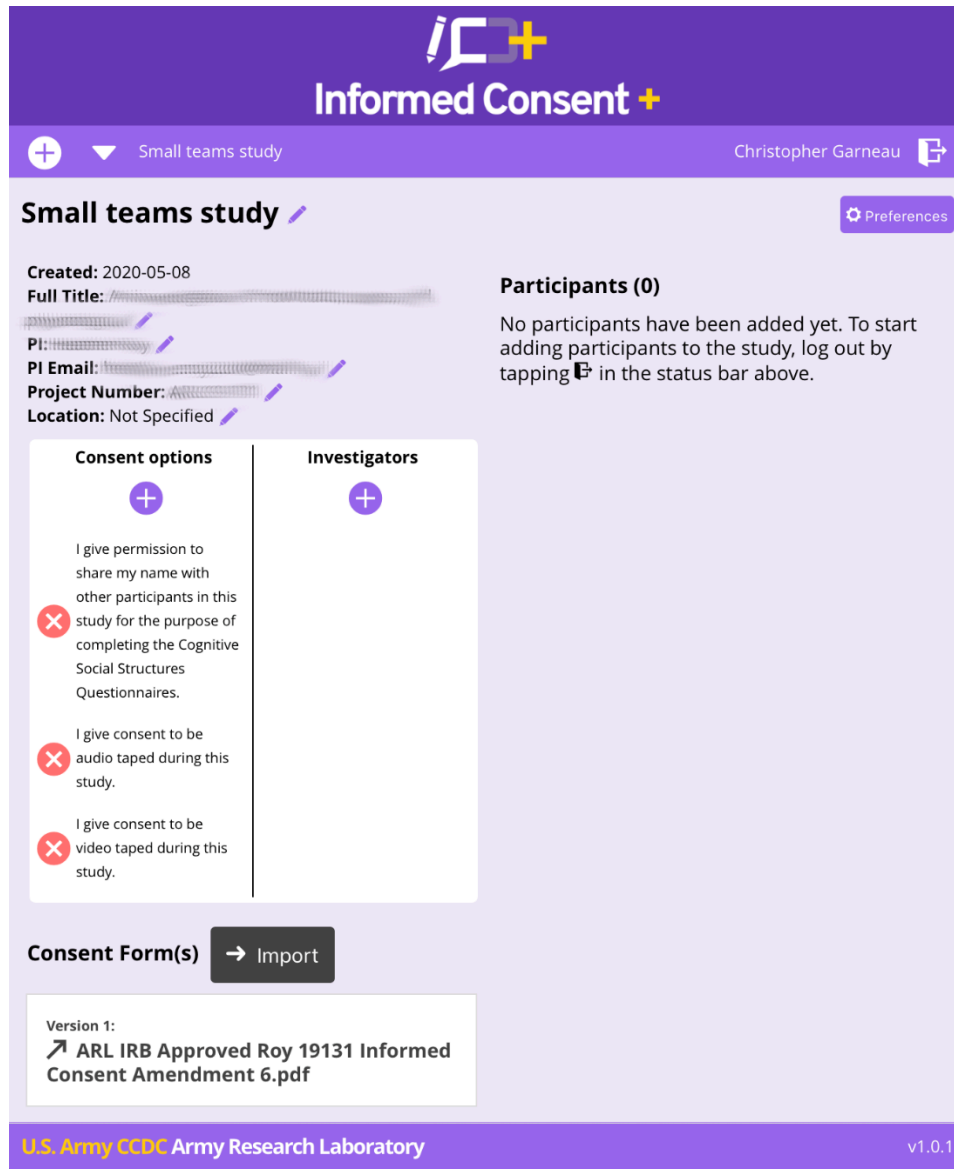


Figure 2. Administration view showing a study having been configured but without any participants having been added

To begin the IC process with participants, the researcher must then log out of their administrator account and lock the app (Figure 3); this presents a simplified view of the app that researchers may hand to participants. Each participant sees an overview of the IC process, the study title, and a single large button labeled as “Review Document and Consent”. Upon tapping this button, they enter their name, provide their email address (optional), and view the PDF consent form (Figure 4).

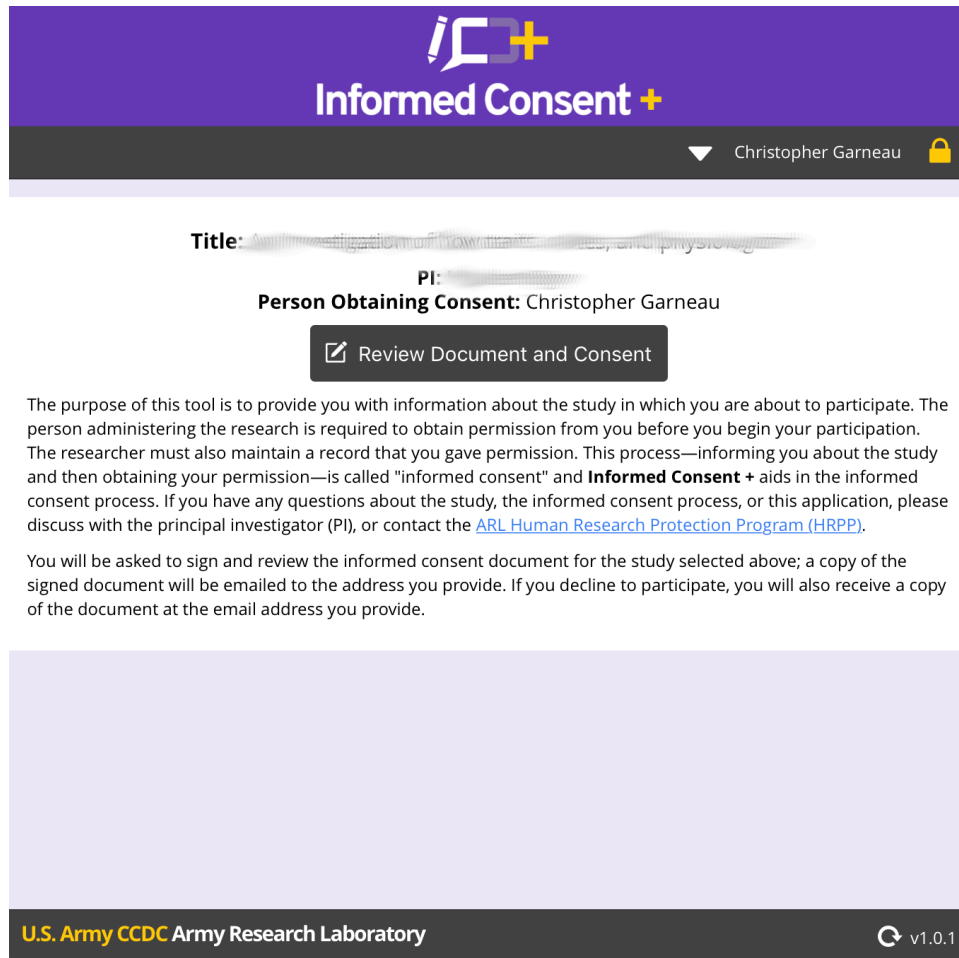


Figure 3 Main view in IC+ locked and ready for participants to consent

Consent Form

← 1 / 7 →

IRB APPROVED
Approved 18 March 2020

Principal Investigator: [REDACTED]
 Version Date: March 16, 2020
 Project Number: [REDACTED]

Research Location(s): Aberdeen Proving Ground, MD, Building 433.

Research Participant Consent Form
Army Research Laboratory

Project Title: [REDACTED]

Sponsor: Department of Defense, Army Research Laboratory

Principal Investigator: [REDACTED]

INTRODUCTION

You are being asked to participate in a research study that is aimed at understanding how certain traits, states, and physiological feedback influence physiological responses and performance while completing a social exchange game and a stress inducing cooperative game with a partner. We expect this study will last approximately nine weeks (but ideally not more than 18 weeks), with one session per week. This schedule could be extended due to scheduling conflicts and make up sessions or extenuating factors (e.g., coronavirus). Each session may last up to three and a half hours. There will be one orientation/training session, followed by eight performance sessions where you will be paired with another study participant to play a couple of games on a desktop computer. You will be paired with a new study participant for each visit. You will also be asked to complete some questionnaires at your orientation visit and at each subsequent visit. At each of the sessions you will be expected to put on some physiological equipment such

U.S. A

Agree
 Decline

v1.0.1

Figure 4. Consent form for the study as displayed in IC+ for participant review

If they agree to participate, the participant is directed to the signature view (Figure 5). They can specify their preference for additional consent options (e.g., being photographed during the study) and provide a signature. Once they tap “Confirm”, their signature is locked and timestamped, and the researcher then provides their signature (which is also timestamped).

Figure 5. Signature view in IC+ after participant reviews consent form and chooses to participate

If the participant has provided an email address and the researcher has elected to have emails automatically generated by IC+, a pre-drafted email will appear using the default email app on the device. If IC+ is running on Android, the signed IC form PDF will be automatically attached to the email; on Windows, the researcher must manually attach the signed IC form. Once the researcher has obtained IC from participants, they can log back in to the administration view to email or export signed IC forms (Figure 6).

The screenshot shows the 'Informed Consent +' administration interface. At the top, the logo and name 'Informed Consent +' are displayed. Below the header, the study name 'Small teams study' is shown with a dropdown arrow and the user 'Christopher Garneau' with an external link icon. A 'Preferences' button is located in the top right.

Study details include:

- Created: 2020-05-08
- Full Title: [Redacted]
- PI: [Redacted]
- PI Email: [Redacted]
- Project Number: [Redacted]
- Location: Not Specified

On the right, the 'Participants (2)' section shows a download button for 'All (.zip)'. Below this, two participants are listed:

- Tom Jones: Consented to version 1 on 2020-05-08, 18:16 GMT (with an envelope icon)
- Susan Smith: Declined (with the word 'Declined' in red)

The main content area is divided into two columns:

- Consent options:** Contains three items, each with a red 'X' icon:
 - I give permission to share my name with other participants in this study for the purpose of completing the Cognitive Social Structures Questionnaires.
 - I give consent to be audio taped during this study.
 - I give consent to be video taped during this study.
- Investigators:** Contains one item with a purple plus icon.

At the bottom left, there is a 'Consent Form(s)' section with an 'Import' button. Below it, a box shows 'Version 1: ARL IRB Approved Roy 19131 Informed Consent Amendment 6.pdf'.

The footer contains 'U.S. Army CCDC Army Research Laboratory' on the left and 'v1.0.1' on the right.

Figure 6. Administration view showing a study having been configured and two participants having consented to participate in the study

3. USABILITY EVALUATIONS

To gather feedback from potential users on the implementation of IC+, two usability evaluations were conducted on IC+ during fall 2018 (FY19) using v0.6 of the app and a two-part evaluation during winter 2020 (FY20). Phase I of the winter 2020 evaluation used v0.8 of the app; Phase II used v1.0. Screenshots of v0.1, v0.6, and v0.8 are presented in Appendices B and C; screenshots of v1.0 appear previously (Figures 1–6). The goal of these evaluations was to assess IC+ performance and identify areas for improvement. One goal of the developers is to ensure that IC+ does not introduce undue complexity compared with the paper-and-pencil IC process.

3.1 2018 Evaluation

For the 2018 evaluation, performance of IC+ was assessed with structured interviews in a user trial with a subset of potential users (researchers) of the system. The sample size was seven individuals.² Participants were presented with several free-response questions to elicit their feedback after a guided tour of the app with a member of the IC+ development team.

The questions were the following:

- How does this process compare with the traditional paper-and-pencil version?
- Do you foresee any potential issues or difficulties in using IC+ for obtaining informed consent?
- What benefits do you foresee in using IC+ for obtaining informed consent?
- What limitations do you foresee?
- Do you have any suggestions for improving or changing IC+?

While these questions yielded a sizable list of comments and suggestions, some of the most salient responses for the indicated prompts were the following:

How does this process compare to paper/pencil?

- IC+ can only consent one person at a time.
- IC+ process is more robust to errors.

Any suggestions for improving or changing IC+?

² This number is in line with standard usability assessment practices (Nielsen, 1994; Nielsen & Landauer, 1993; Baxter et al., 2015)

- More “dummy proofing” is needed.
- Provide a way to compile ICs for participants when multiple researchers obtain consent.
- Provide a way to increase text size in App and on IC.
- The process to email the IC is time consuming.

Would this app be useful for your data collection effort?

- Yes (4), Maybe (1), No Answer (2)

What benefits do you foresee in using this app for obtaining IC?

- More secure data management, tracking, and IRB compliance
- Will ensure all aspects of IC forms are complete.

In addition to soliciting specific suggestions to improve the interface or usability, the evaluation also asked users to rate how easy or difficult it was to perform specific tasks. Table 1 shows the tasks and response distribution for ease of use.

Table 1. Responses from the Seven Potential Users of the System for Ease of Use for the Fall 2018 Evaluation

Task	Very Easy	Easy	Neutral	Difficult	Very Difficult
Create user account	86%	14%	0%	0%	0%
Create study	86%	14%	0%	0%	0%
Upload IC	86%	14%	0%	0%	0%
Configure options	71%	29%	0%	0%	0%
Initiate session	71%	29%	0%	0%	0%
Add participant	86%	14%	0%	0%	0%
Obtain consent	86%	0%	14%	0%	0%
Access list of participants	86%*	14%	0%	0%	0%
Access signed IC forms	71%*	14%	14%	0%	0%
Email signed IC forms	29%	14%	43%	14%	0%

Most of the specific suggestions elicited from this usability evaluation were implemented in a subsequent version of IC+.

3.2 Winter 2020 Evaluation, Phase I

For the first phase of the winter 2020 evaluation, performance of IC+ was assessed via an ease-of-use questionnaire (with the option for free-response comments) and the System Usability Scale (SUS [Brooke, 1986]). The participant pool consisted of seven CCDC Army Research Laboratory researchers identified as having submitted a protocol or determination for a current or recent study approved by the HRPP.³ These researchers were different from those contacted during the fall 2018 evaluation. Participants first watched a member of the IC+ development team walk through the steps to create an administrator account, set up a study, obtain IC, and so on. Next, they were given a worksheet of the tasks they just watched and had 10–15 min to complete the set of tasks. For each task, they were asked to rate the ease of completing the task and they were also presented with space for additional comments. The last section of the worksheet asked participants to complete the SUS questionnaire after completing all tasks. Table 2 shows the tasks and response distribution for ease of use. Note that tasks in Table 2 closely correlate with tasks in Table 1, though the wording slightly changed for some tasks.

Table 2. Winter 2020 Phase I Ease of Use Results

Task	Very Easy	Easy	Neutral	Difficult	Very Difficult
Create a new administrator account	71%	29%	0%	0%	0%
Create a new study	71%	29%	0%	0%	0%
Upload IC form	100%	0%	0%	0%	0%
Configure study options (e.g., PI name, audio/video consent, etc.)	86%	14%	0%	0%	0%
Initiate an IC session	57%	29%	14%	0%	0%
Add a new participant	71%	29%	0%	0%	0%
Obtain consent/signature	100%	0%	0%	0%	0%
Access list of participants	43%	43%	14%	0%	0%
Access signed IC forms	86%	14%	0%	0%	0%
Email signed IC forms	57%	29%	14%	0%	0%

Comments provided for each of the tasks yielded a few common recommendations:

- The mechanism for creating an administrator account, building a study, and then logging out and selecting an active study or administrator seemed too cumbersome to several participants.

³ Twenty-two researchers were contacted, yielding a response rate of 31%.

- Multiple participants recommended that an indication be provided in the administrator view as to whether or not an email was automatically generated for a given study participant (since the administrator has the option to generate one or skip this during the IC process).
- Multiple participants recommended providing a mechanism for generating an email from the administrator view in case this option was not selected during the IC process.

Among the seven participants, IC+ scored an 81 on the SUS. This indicates that the IC+ score is between “good” and “excellent”. Figure 7 shows a benchmark reference for interpreting overall SUS scores normalized on a 100-point scale. Future usability evaluations might consider including the SUS questionnaire to compare performance improvement (or degradation) as changes are made to the app.

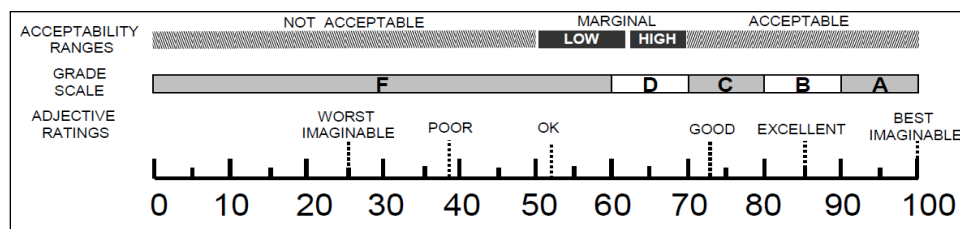


Figure 7. Benchmark normalized SUS scores

3.3 Winter 2020 Evaluation, Phase II

For the second phase of the winter 2020 evaluation, performance of IC+ was assessed via a field study wherein IC+ was presented as an alternative to a traditional paper-and-pencil informed consent form for a current ARL study: ARL 19-131, *An investigation of how traits, states, and physiological feedback influence physiological synchrony and task performance in small teams*. The main purpose of this evaluation was to capture any feedback and identify any system errors from researchers and participants. As noted earlier, this phase of the evaluation used IC+ v1.0, which incorporated feedback from the Phase I evaluation.

The researchers running the study (and obtaining consent from participants) noted no significant issues with using the app and received generally positive feedback from participants. Study participants (who were also researchers in ARL) provided the following comments:

- It was not clear how to receive a copy of the signed IC as there was not a place to request a copy.
- Multiple participants did not realize for the signature block that they were supposed to write in it. One thought a certificate (digital signature) would automatically pop up like on their ARL machines. Therefore, they only made a dot and confirmed.

-
-
- The selection options for Yes or No buttons was a single button where the participant could tap and the one marked swaps. The recommendation was to make this radio buttons with both options visible.
 - One participant found it “weird” to review the PDF and sign on a different screen rather than initial and sign within the actual document. Another person recommended that instead of having agree or decline on the PDF signature line, make it “next” since it makes it sound like you are agreeing to the whole thing then but really you are doing that on the next page after you make all your selections and sign.
 - One participant found the zoom functionality of the PDF and requirement to scroll “annoying”. Another person recommended making the PDV infinitely scrollable (personal preference).
 - *The app lets you change your response for the optional selections after you sign so would be better to lock your responses.*
 - *The system did not recognize email (ctr) as a valid email address.*

For the most part, the comments above reflect limitations of the device, limitations of the development framework, or personal preference. However, the last two italicized items represent bugs that will be fixed in the v1.0.2 update.

4. CONCLUSIONS AND FUTURE WORK

IC+ has been developed as a way to obtain IC from participants in an offline research environment for studies involving human participants under HRPP oversight. The app has been tested among users within ARL, with positive feedback indicating that it is likely to achieve its objective of improving the convenience of the IC process for researchers and study participants as well as reducing the number of errors commonly seen on IC forms. The software is available for researchers to download from the ARL shared drive as a Windows portable application; packages for other platforms are available upon request. The HRPP office maintains a tutorial for using the software in studies and also maintains a limited pool of tablet hardware available for checkout by ARL researchers. Future versions of the IC+ app presented in this report will focus on the addition of new features or modifications to address researcher feedback and resolving the identified system errors.

IC+ (v1.0) has the ability to improve in-person administration of IC in an offline environment. However, this implementation of IC+ does not address situations where IC must be obtained remotely with the researcher and participant in physically distant locations completing internet-based study tasks. This scenario may become increasingly common in remote-working scenarios and introduces at least three main challenges: 1) ensuring comprehension to obtain *informed* consent, 2) ensuring that the person providing consent is the person participating in the research, and 3) developing a system that incorporates network connectivity and storage facilities to administer and manage the IC forms remotely. To address the first challenge, others have proposed an interactive or wizard-based system to walk participants through study procedures and expectations (e.g., Abujarad et al., 2018; Doerr et al., 2016). Any implementation of a remote IC system would likely need to provide a more thorough overview of the study in an engaging and easy-to-navigate format. A digital version of the traditional paper IC form would not be sufficient. Addressing the second and third challenges requires digital solutions that provide appropriate levels of security for participant identity and their data. Provided funding and the appropriate network resources, addressing these identified challenges will be the focus of future development of a cloud-based version of IC+.

Whether using the offline version of IC+ discussed in this report or a future cloud-based IC+, the main goals of the app are to enhance convenience for both researchers and participants and reduce errors that commonly occur on IC forms. Future evaluations of either version of the app should determine whether (and to what extent) IC+ reduces the number of IC form-related findings on audits compared with historical data as well as any studies using traditional IC forms (not using IC+). This will enable continuous improvement of the app(s). It will also provide evidence for continued investment in new tools and processes for the administration of human research protection, both within and beyond ARL.

5. REFERENCES AND DOCUMENTS

- Abujarad, F., Alfano, S., Bright, T. J., Kanoth, S., Grant, N., Gueble, M., Peduzzi, P., & Chupp, G. (2018). *Building an Informed Consent Tool Starting with the Patient: The Patient-Centered Virtual Multimedia Interactive Informed Consent (VIC)*. AMIA Annual Symposium proceedings. AMIA Symposium, 2017, 374–383.
- Baxter, K., Courage, C., & Caine, K. (2015). *Understanding your users: A practical guide to user research methods*. Morgan Kaufmann.
- Brooke, J. (1986). *SUS: a “quick and dirty” usability scale*. In P. W. Jordan, B. Thomas, B. A. Weerdmeester, & A. L. McClelland (eds.). *Usability Evaluation in Industry*. Taylor and Francis.
- Doerr, M., Suver, C., & Wilbanks, J. (2016, April 22). *Developing a transparent, participant-navigated electronic informed consent for mobile-mediated research*. Participant-Navigated Electronic Informed Consent for Mobile-Mediated Research.
- Friedlander, J. A., Loeben, G. S., Finnegan, P. K., Puma, A. E., Zhang, X., De Zoeten, E. F., ... & Mamula, P. (2011). A novel method to enhance informed consent: a prospective and randomised trial of form-based versus electronic assisted informed consent in paediatric endoscopy. *Journal of Medical Ethics*, 37(4), 194–200.
- Nielsen, J. (1994). *Heuristic evaluation. Usability inspection methods*. John Wiley & Sons, Inc.
- Nielsen, J. & Landauer, T. K. (1993). A mathematical model of the finding of usability problems. *Proceedings of the INTERACT'93 and CHI'93 conference on Human factors in computing systems*. ACM.
- Obeid, J. S., Gerken, K., Madathil, K. C., Rugg, D., Alstad, C. E., Fryar, K., Alexander, R., Gramopadhye, A. K., Moskowitz, J., & Sanderson, I. C. (2013). *Development of an electronic research permissions management system to enhance informed consents and capture research authorizations data*. AMIA Joint Summits on Translational Science proceedings. AMIA Joint Summits on Translational Science, 2013, 189–193.
- Rothwell, E., Wong, B., Rose, N. C., Anderson, R., Fedor, B., Stark, L. A., & Botkin, J. R. (2014). A randomized controlled trial of an electronic informed consent process. *Journal of Empirical Research on Human Research Ethics*, 9(5), 1–7.
- U.S. Food and Drug Administration. (2016). *Use of electronic informed consent, questions and answers: Guidance for institutional review boards, investigators, and sponsors*. U.S. Food and Drug Administration.

U.S. Food and Drug Administration. (2018). *FDA's MyStudies Application (App)*.
<https://www.fda.gov/drugs/science-and-research-drugs/fdas-mystudies-application-app>

Appendix A – List of Acronyms

app	application
ARL	Army Research Laboratory
CCDC	U.S. Army Combat Capabilities Development Command
COTS	commercial off-the-shelf
HRPP	Human Research Protection Program
IC	informed consent
IC+	Informed Consent +
IRB	Institutional Review Board
PDF	Portable Document Format
SUS	System Usability Scale

Appendix B – Informed Consent + (IC+) Prototype (v0.1)

Figures B-1 through B-4 provide screenshots of the first prototype version of the Informed Consent + (IC+) application (app) (v0.1) outlining preliminary functionality. The prototype app provides both a researcher view for setting up the study and participant view for obtaining consent. Figure B-1 depicts the researcher view. Researchers are able to add new studies into the app by selecting the + sign or view previously added studies by selecting one from the drop-down menu. From this page, it is also possible to view or export a list of participants for a given study.

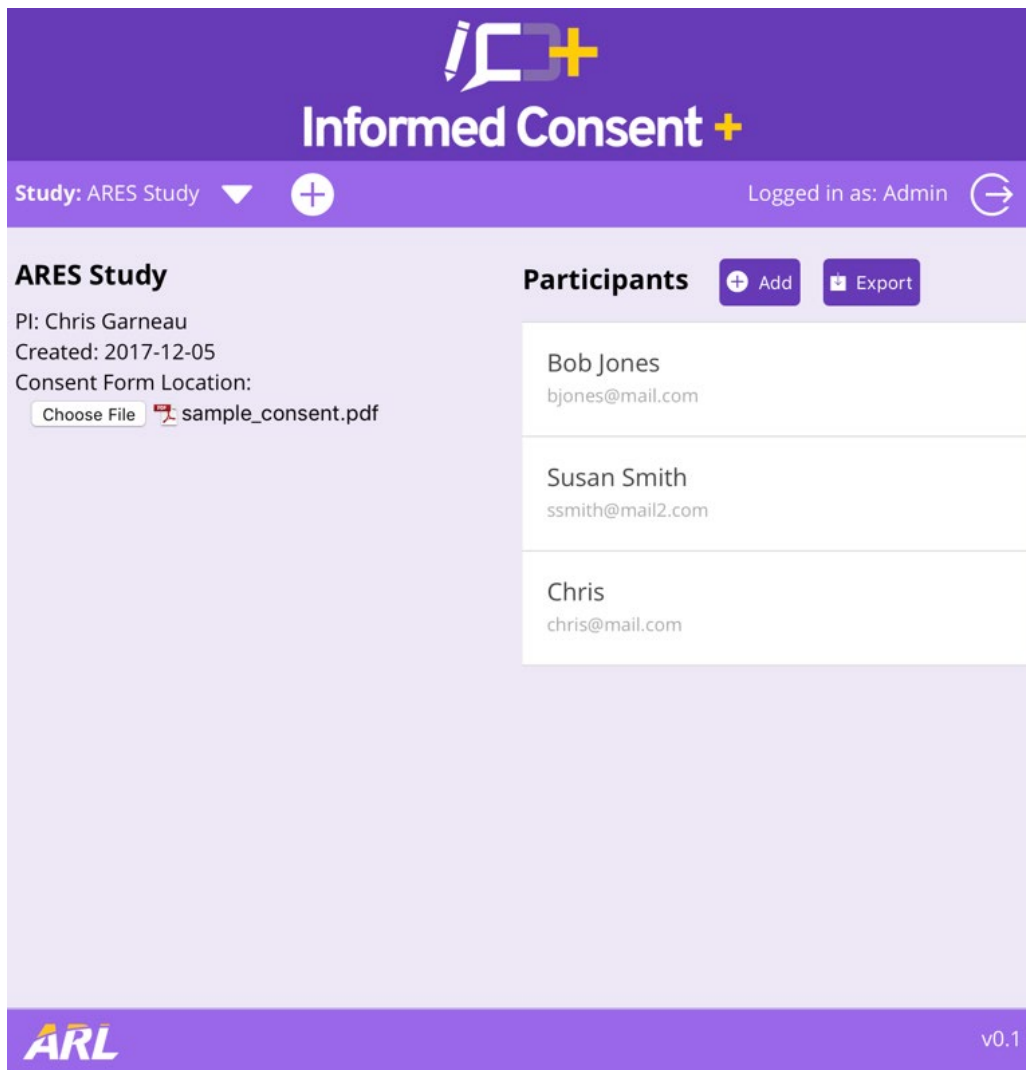


Figure B-1. Researcher view for adding new studies or monitoring participants of an ongoing or concluded study

When a researcher selects the option to add a study, they will add the study title, principal investigator (PI) (Figure B-2) and upload the approved file (in PDF format) of the informed consent (IC) document (Figure B-3). Researchers will also be able to select additional consent options such as audio or video recording. Once the researcher has completed study setup, they

can begin obtaining IC from participants. To do this, they must click the “Add” button next to the “Participants” title. When they do so, a popup asks for the participant’s name and email (Figure B-4). When the participant provides this information, they are directed to view the PDF IC document (see Figure B-3). While not implemented in v0.1.0, the next step would be for the participant to provide a timestamped digital signature, which is logged in the app along with the researcher’s signature.



Figure B-2. To create a new study, users will need to add the study title so they are able to differentiate between their studies on the app; the PI name should be the full name of the PI. It is used by the app to add a printed name to the electronic signature

Consent Form✕

sample_consent.pdf

◀+⌂-↻▶

Page: / 3

Date: 05/18/2016
Principal Investigator: [REDACTED]
Project No.: [REDACTED]

Site of Research: [REDACTED]

RESEARCH PARTICIPANT CONSENT FORM
ARMY RESEARCH LABORATORY

Project Title: [REDACTED]

Sponsor: Army Research Laboratory (Internal Postdoc Project)

Principal Investigator: [REDACTED]
Address: [REDACTED]
Phone Number: [REDACTED]
E-mail: michael.[REDACTED]

Date: 05/18/2016

✓ Agree✕ Decline

Figure B-3. Consent form view for participants, the approved PDF from the IRB office. Participants can scroll through multiple pages by selecting the forward or back arrows, and agree or decline participation. If they agree to participation, a signature window opens.

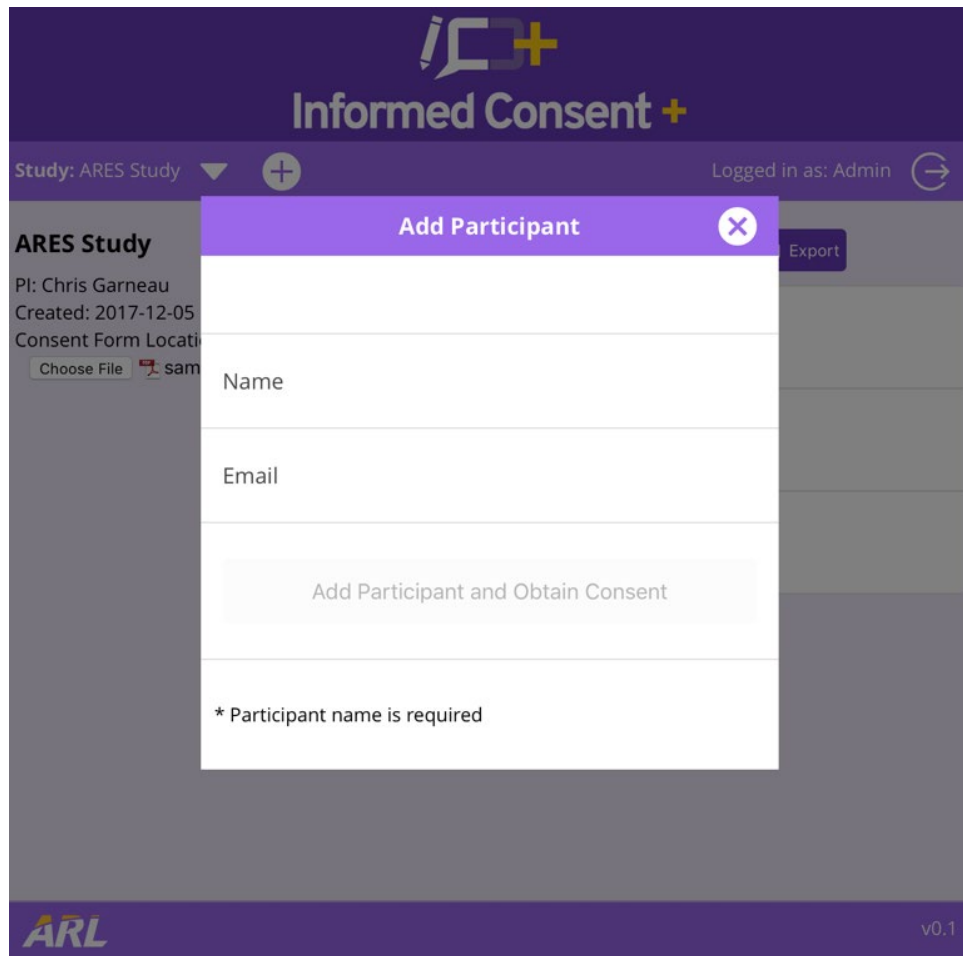


Figure B-4. Each participant adds their full name (as it provides a printed name to the signature block) and may provide an email address. An email address is needed to receive an electronic version of the signed IC form

Appendix C – Informed Consent + (IC+) v0.6 and v0.8 from Usability Evaluations

C.1 IC+ v0.6 screenshots

Figures C-1 through C-6 depict Informed Consent + (IC+) v0.6, used in the fall 2018 evaluation.

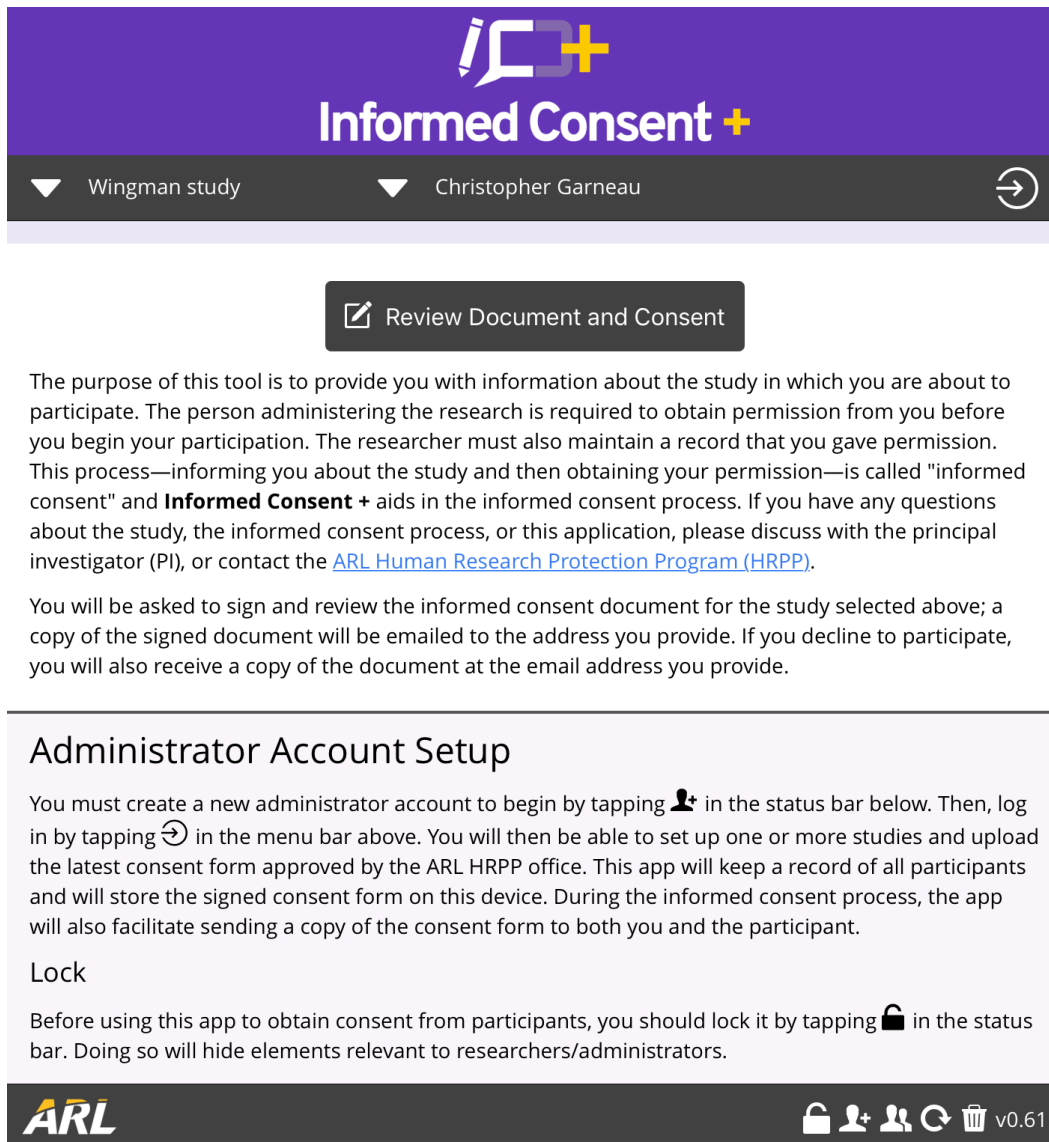


Figure C-1. Home screen (unlocked)

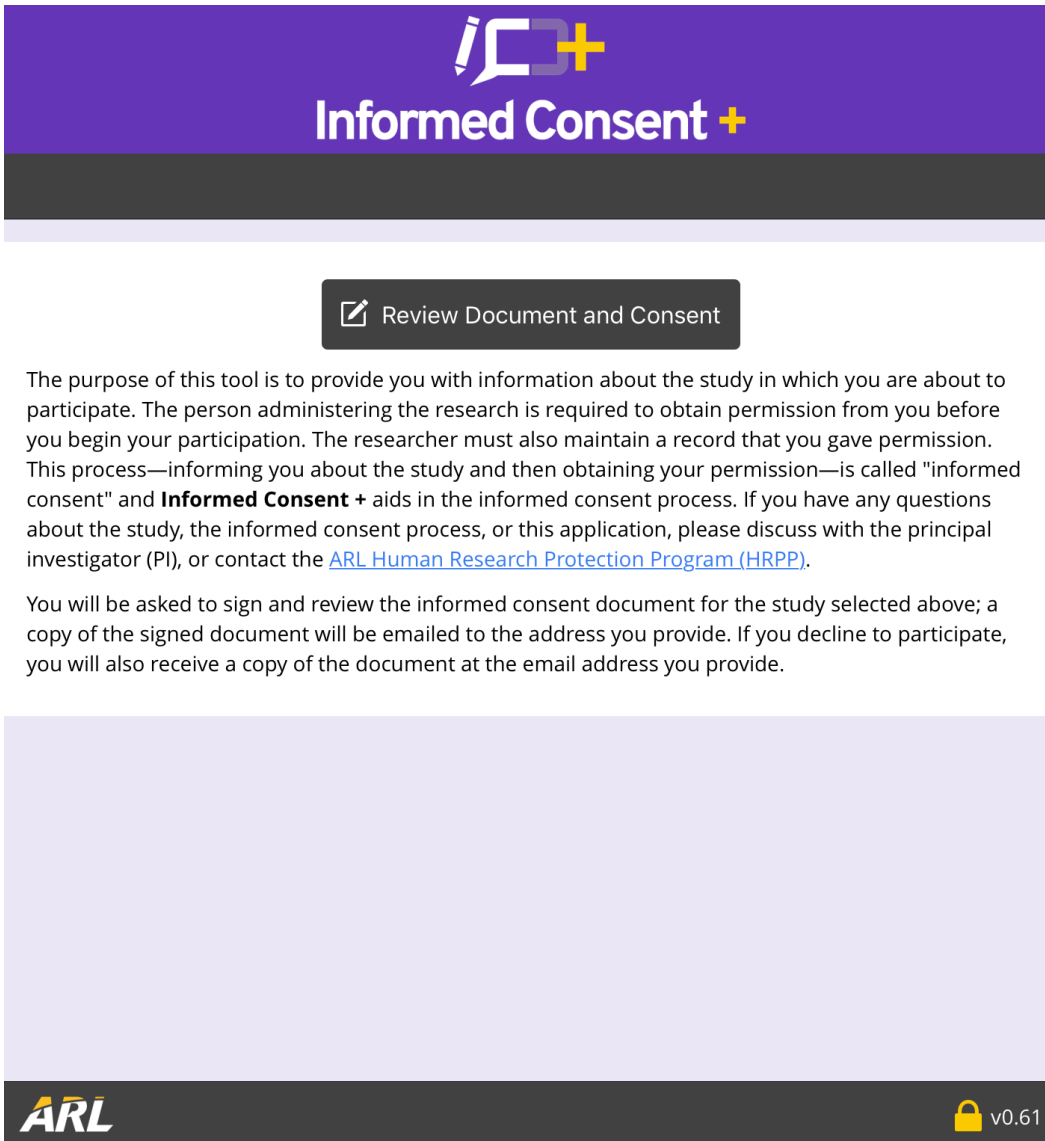


Figure C-2. Home screen (locked for administration of informed consent [IC])

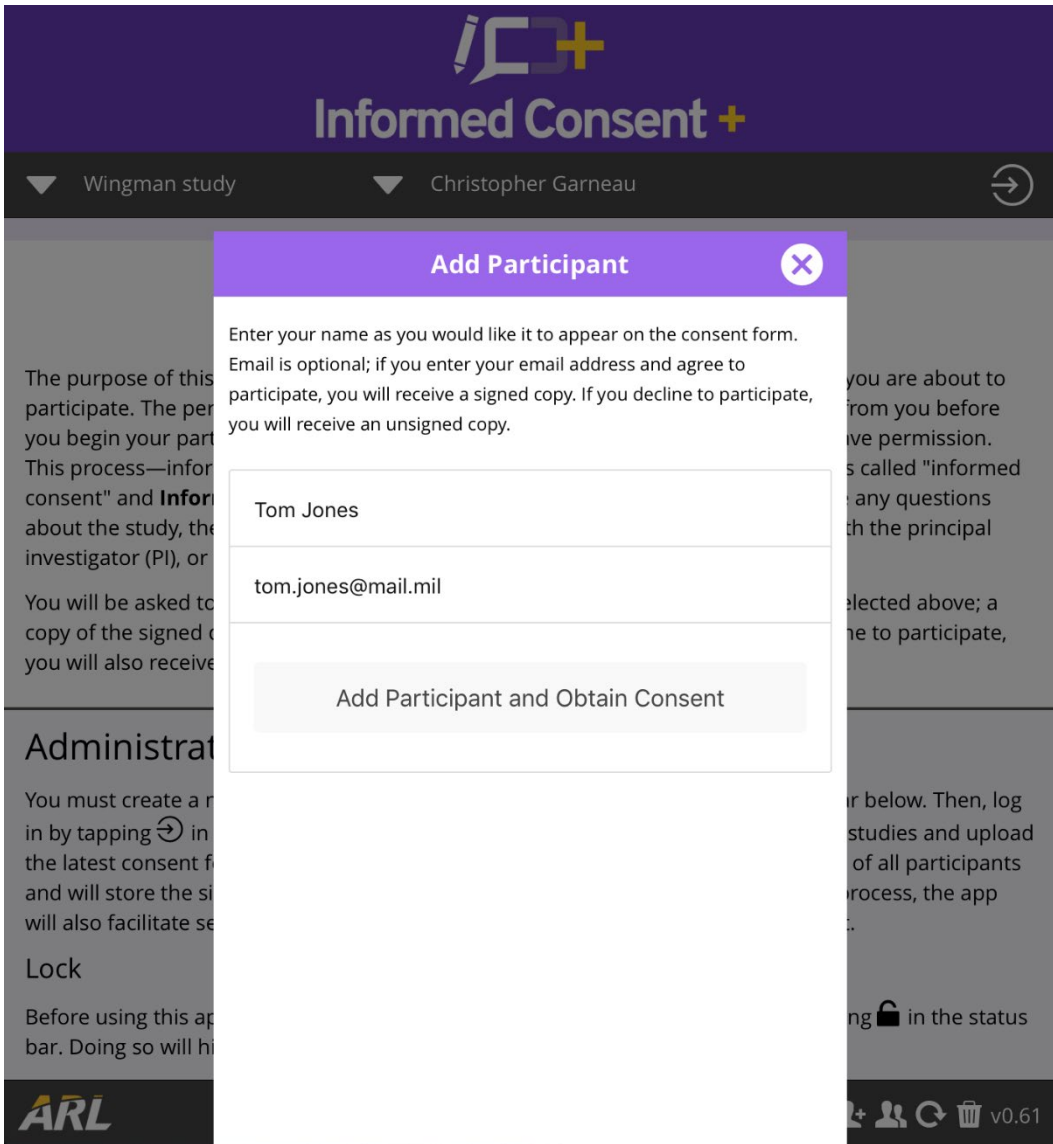


Figure C-3. Participant input of name and email address



Principal Investigator: [REDACTED]
Version Date: 17 Oct. 2017
Project Number: [REDACTED]

Site of Research: Aberdeen Proving Ground, MD

**RESEARCH PARTICIPANT CONSENT FORM
ARMY RESEARCH LABORATORY**

Project Title: [REDACTED]
Sponsor: Department of Defense, Army Research Laboratory
Principal Investigator: [REDACTED]

You are being asked to join a research study. This consent form explains the research study and your part in it. Please read this form carefully before you decide to take part. You can take as much time as you need. Please ask questions at any time about anything you do not understand. You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part right now or you can quit at any time later on.

Why is this research being done?

This research study will assess features and usability of a user display (Warfighter Machine Interface) developed for manned-unmanned teaming for the US Army TARDEC Wingman program. Outcomes from this study will provide guidance and feedback to the developers of the WMI and develop initial training protocols for Soldiers to effectively use the interface for

Agree Decline

Figure C-4. Participant view of administrator-uploaded IC form

Consent Form: Signature✕

Additional Consent Options


We would like your permission to record you during the research session. Please check the boxes below if you will agree to allow us to record you using the given medium(s).

I give consent to be videotaped during this study.

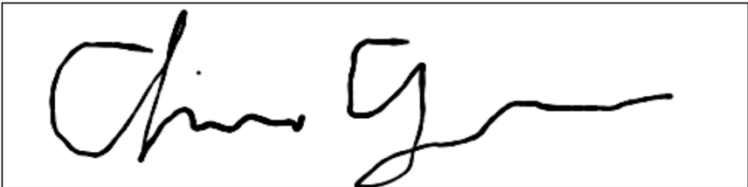
I give consent to be photographed during this study.

Consent Signature

I confirm that I have read the preceding pages of the informed consent form, understand the provisions therein, and agree to participate in the study.



Tom Jones ✕ Clear ✎ Sign



Christopher Garneau ✕ Clear ✎ Sign and Save

(person obtaining consent)

✕ Decline

Figure C-5. Participant signature screen

Informed Consent +

Wingman study Logged in as: chris

Wingman study

Created: 2018-06-14
Title (official): [Redacted]
PI: [Redacted]
ARL Project Number: [Redacted]

Additional consent options

- Audio Recording
- Video Recording
- Photograph

Consent Form(s) +

Version 1:
 [Icon] ARL_17-248.pdf

Participants (2) ↓ All (.zip)

Bob Jones	Declined
[Icon] Tom Jones	Consented to version 1 on 2018-06-14, 22:01 GMT

ARL v0.61

Figure C-6. Study administration screen for research administrator

C.2 IC+ v0.8 screenshots

Figures C-7 through C-10 depict IC+ v0.8, used in the first phase of the winter 2020 evaluation.

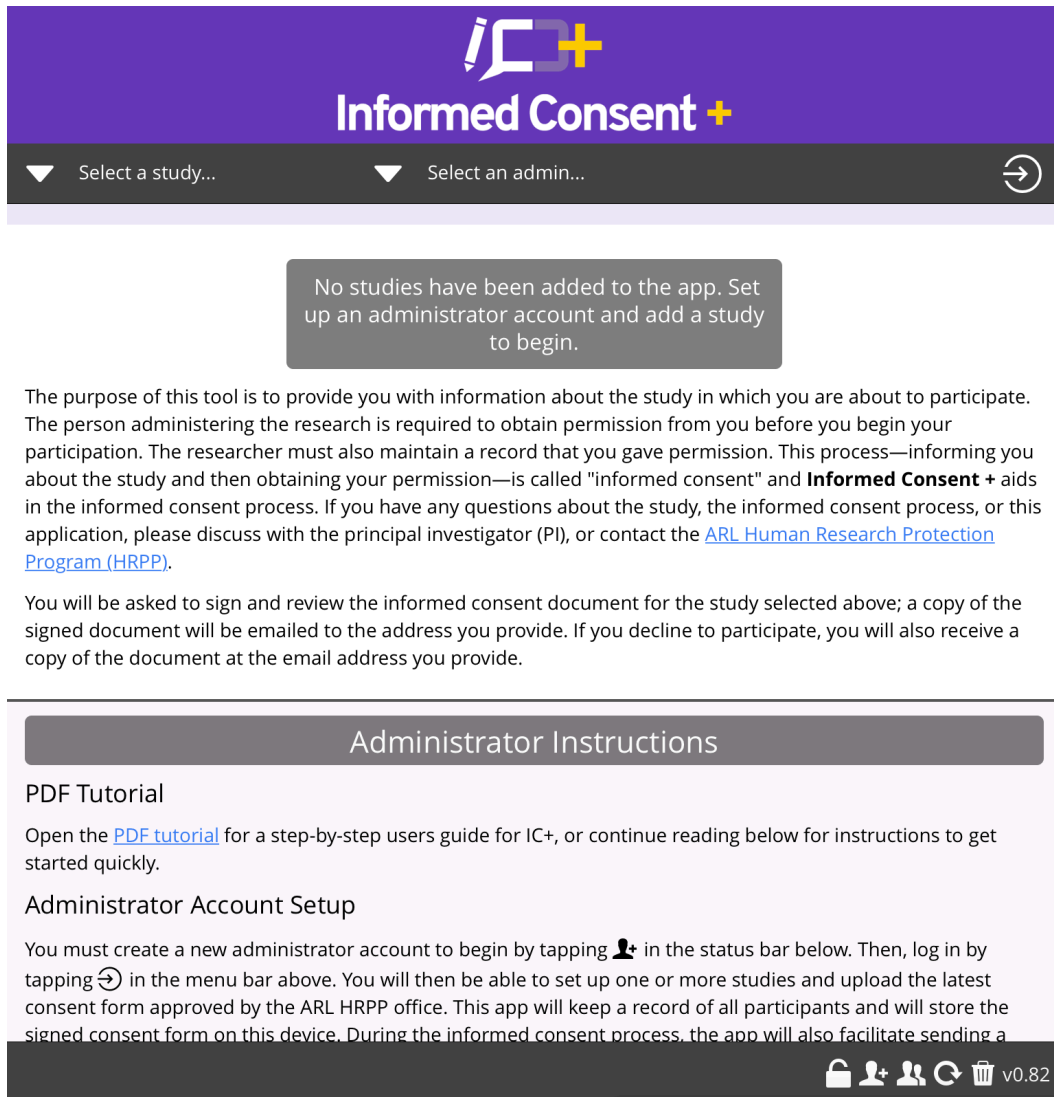


Figure C-7. Initial home screen (unlocked)



Figure C-8. Sample home screen (locked for administration of IC)

Additional Consent Options


We would like your permission to record you during the research session. Please check the boxes below if you will agree to allow us to record you using the given medium(s).

I give consent to be audio taped during this study. Yes No

I give consent to be photographed during this study. Yes No

Consent Signature

I confirm that I have read the preceding pages of the informed consent form, understand the provisions therein, and agree to participate in the study.



Jane Jones

Christopher Garneau

(person obtaining consent)

Figure C-9. Participant signature screen

The screenshot shows the 'Informed Consent +' interface for a study named 'Wingman study'. The user is logged in as 'chris'. The study details include: Created: 2019-06-03, Title (official): [redacted], PI: [redacted], PI Email: [redacted], ARL Project Number: [redacted], and Location: APG. Under 'Additional consent options', 'Audio Recording' and 'Photograph' are selected, while 'Video Recording' is not. A 'Consent Form(s)' section shows 'Version 1: ARL_17-248.pdf'. A 'Participants (5)' list shows: Bob Smith (Consented to version 1 on 2019-06-10, 22:27 GMT), Tom Jones (Consented to version 1 on 2019-06-10, 22:36 GMT), Jane Jones (Declined), Tim Barton (Consented to version 1 on 2019-06-13, 21:38 GMT), and Mary Jones (Consented to version 1 on 2019-06-14, 17:19 GMT). The version number v0.82 is displayed in the bottom right corner.

Figure C-10. Sample study administration screen for research administrator

Appendix D – Distribution List

ORGANIZATION

U.S. Army CCDC Data & Analysis Center
FCDD-DAD-OL/T. Resetar-Racine
FCDD-DAS-LHC/C. Garneau
6896 Mauchly Street
Aberdeen Proving Ground, MD

U.S. Army CCDC Army Research Laboratory
FCDD-RLD-CL/Tech Library
2800 Powder Mill Rd.
Adelphi, MD 20783

Defense Technical Information Center
ATTN: DTIC-O
8725 John J. Kingman Rd.
Fort Belvoir, VA 22060-6218

U.S. Army CCDC Army Research Laboratory
FCDD RLH B/T, Davis
Bldg 5400 RM C242
Redstone Arsenal, AL 35898-7290

U.S. Army CCDC Army Research Laboratory
FCDD HIS/J. Thomas
6662 Gunner Circle
Aberdeen Proving Ground, MD 21005-5201

U.S. Air Force 711 HPW
711 HPW/RH/K Geiss
2698 G St., Bldg 190
Wright Patterson AFB, OH 45433-7604

U.S. Navy Office of Naval Research
ONR CODE 341/J. Tangney
875 N Randolph St., Bldg 87
Arlington VA, 22203-1986

U.S. Army NSRDEC
RDNS D/D. Tamilio
10 General Greene Ave
Natick, MA 01760-2642

Office of the Secretary of Defense OUSD ATL
HPT&B/B. Petro
4800 Mark Center Dr., Ste 17E08
Alexandria, VA 22350

U.S. Army CCDC Army Research Laboratory
FCDD RLH
T. Straut
J. Biladeau
K. E. Schaefer
J. Lane
J. Y. C. Chen
P. Franaszczuk
A. Marathe
K. Mcdowell
K. Oie
FCDD RLH F
J. Gaston (A)
FCDD RLH FA
A. Decostanza
FCDD RLH FB
D. Boothe (A)
FCDD RLH FC
K. Cox (A)
FCDD RLH FD
A. Fouts (A)
FCDD RLH FE
D. Headley
Aberdeen Proving Ground, MD