



REDCap Training for eConsent



THE OHIO STATE UNIVERSITY
CENTER FOR CLINICAL AND
TRANSLATIONAL SCIENCE

© May 2022– Amanda Carroll

This work is licensed under a [Creative Commons Attribution 3.0 Unported License](https://creativecommons.org/licenses/by/3.0/).



THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

Agenda

- REDCap Services
- Logging in to REDCap
- General Information about eConsent
 - To Sign or Not to Sign
 - Waiver of Consent Documentation
 - Signature Required/ Not Required
- Current eConsent Process
- New eConsent Process/ Template
 - How to use it
 - (Setup will be reviewed in September)
- Notes
- New eConsent Template Request Process

REDCap Services

<https://u.osu.edu/redcap/>

- Grand Rounds
 - 2nd Tuesday of each month @ 11am
- Monthly Trainings
 - 4th Wednesday of each month @ 12pm
 - Design 1, Design 2, Data Entry & Program Management, eConsent (NEW!)
- Office Hours
 - Mondays 11am-1pm & Wednesdays 1pm-3pm
 - Drop-in through Zoom link (on website)
- Thursday Consults
 - Form Reviews, Initial Consult, Troubleshooting, eConsent (NEW!)
 - Scheduled: link on website

Two Distinct Instances

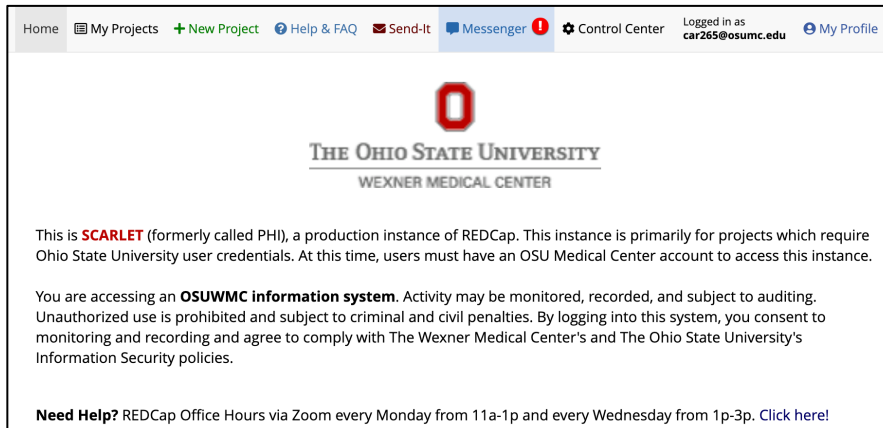
- **Scarlet (formerly called PHI)**
 - Behind OSUMC access firewall
 - Requires OSUMC Wireless, VPN, or Duo to login
 - Currently requires OSUMC credentials for login
 - Can hold up to S4 Data (PHI and FERPA)
 - <https://redcap.osumc.edu/>
- **Gray (formerly called non-PHI)**
 - Reserved for multi-site/ multi-institutional projects with external users
 - Also for non-human subject research
 - Login and password specific to REDCap
 - <https://redcap.bmi.osumc.edu/>

Logging In


Open a web browser
Type in the URL



- Scarlet - <https://redcap.osumc.edu/>



Home My Projects + New Project Help & FAQ Send-It Messenger Control Center Logged in as car265@osumc.edu My Profile

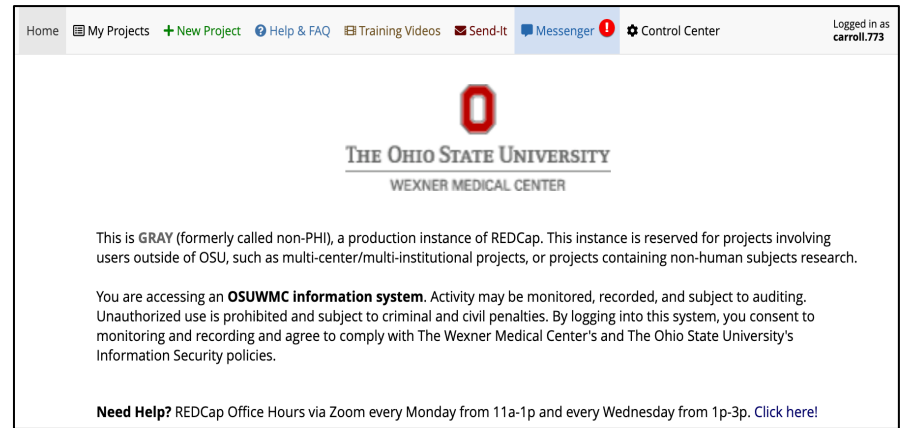

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

This is **SCARLET** (formerly called PHI), a production instance of REDCap. This instance is primarily for projects which require Ohio State University user credentials. At this time, users must have an OSU Medical Center account to access this instance.


You are accessing an **OSUWMC information system**. Activity may be monitored, recorded, and subject to auditing. Unauthorized use is prohibited and subject to criminal and civil penalties. By logging into this system, you consent to monitoring and recording and agree to comply with The Wexner Medical Center's and The Ohio State University's Information Security policies.

Need Help? REDCap Office Hours via Zoom every Monday from 11a-1p and every Wednesday from 1p-3p. [Click here!](#)

- Gray - <https://redcap.bmi.osumc.edu/>



Home My Projects + New Project Help & FAQ Training Videos Send-It Messenger Control Center Logged in as carroll.773


THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

This is **GRAY** (formerly called non-PHI), a production instance of REDCap. This instance is reserved for projects involving users outside of OSU, such as multi-center/multi-institutional projects, or projects containing non-human subjects research.

You are accessing an **OSUWMC information system**. Activity may be monitored, recorded, and subject to auditing. Unauthorized use is prohibited and subject to criminal and civil penalties. By logging into this system, you consent to monitoring and recording and agree to comply with The Wexner Medical Center's and The Ohio State University's Information Security policies.

Need Help? REDCap Office Hours via Zoom every Monday from 11a-1p and every Wednesday from 1p-3p. [Click here!](#)



General Information



eConsent Information

Basics

- Electronic informed consent (eConsent) is a method of obtaining informed consent using electronic media (i.e REDCap)
- Can supplement or replace paper-based informed consent forms
- Can be used in-person and/or remotely
- In order to use eConsent for a study, IRB approval must be obtained

To Sign or Not to Sign?

- Participant signature is not necessarily required
 - Usually not required if it is a minimal risk study
- Check the guidelines for Documentation of Informed Consent (ORRP Policy #20)
<http://orrp.osu.edu/files/2011/10/Documentation-of-Informed-Consent.pdf>
- ***Specifically***, Section 9 starting on Page 3 “Waiver of Documentation of Informed Consent”

Requesting a Waiver

- If your study meets criteria, indicate Waiver of Consent Documentation on the Buck-IRB screen


Informed Consent Process

All fields marked with an * are required.

See [Consent for Research](#) for templates, HRPP policies [Informed Consent Process and the Elements of Informed Consent](#), [Documentation of the Informed Consent Process](#) and [Assent and Parental Permission](#) or contact ORRP for more information.

Indicate the consent process(es) to be used in the study. Check all that apply.*

<input type="checkbox"/>	Informed Consent - Form
<input type="checkbox"/>	Informed Consent - Verbal Script/Online
<input type="checkbox"/>	Informed Consent - Addendum
<input type="checkbox"/>	Alteration of Consent Process
<input type="checkbox"/>	Alteration of Parental Permission
<input type="checkbox"/>	Assent - Form
<input type="checkbox"/>	Debriefing Script
<input type="checkbox"/>	Assent - Verbal Script/Online
<input type="checkbox"/>	Parental Permission - Form
<input type="checkbox"/>	Parental Permission - Verbal Script/Online
<input type="checkbox"/>	Translated Consent/Assent - Form(s)
<input type="checkbox"/>	Waiver of Assent
<input type="checkbox"/>	Waiver of Consent Process
<input type="checkbox"/>	Waiver of Consent Documentation
<input type="checkbox"/>	Waiver of Parental Permission
<input type="checkbox"/>	Waiver of Parental Permission Documentation



Signature Not Required

Study has obtained a Waiver of Documentation (usually minimal risk)

- The consent can be designed with a statement at the end where the participant can indicate agreement to participate
 - Do not have to use the new eConsent framework template

The screenshot displays a web-based consent form interface. The top section, titled 'Variable: providing_consent', contains the following text: 'Providing consent: I have read (or someone has read to me) this page and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by agreeing to participate. To print or save a copy of this page, select the print button on your web browser. Please click the button below to proceed and participate in this study. If you do not wish to participate, please close out your browser window.' Below this text are two buttons: 'Add Field' and 'Add Matrix of Fields'. The bottom section, titled 'Variable: consent_agree', features a red asterisk and the text '* must provide value'. It contains a radio button followed by the text 'I voluntarily agree to participate in this study.' and a 'reset' link. This section also includes 'Add Field' and 'Add Matrix of Fields' buttons.

Signature Required

Study does not meet criteria for a Waiver of Documentation

- There are three approved methods for obtaining an electronic signature in REDCap
 - In-person
 - Pre-established passcode (most common)
 - Using information known to the participant, which is stored in REDCap
 - Using PHI/PII as a passcode is the last resort
- **REDCap eSignature 21 CFR Part 11 capable coming soon!**

Approved eConsent Method: Passcode

- Using a pre-established passcode provided by the participant
 - Create a field in REDCap to store the password
 - Participant authenticates to the survey using the same password
 - The passcode populated **before** distributing the link
 - You cannot send the passcode to the participant in an email. The passcode is only to be created/given over the telephone or in person when you can verify the identity of the person you are speaking to.



Old Process



Informed Consent and HIPAA Template

- Informed Consent form can be created in REDCap as a survey (alone or along with other CRFs)
- A template using the Combined Consent & HIPAA Authorization Template from ORRP website is available in REDCap Shared Library
- Template includes HIPAA section, can be deleted if not needed

Data Collection Instruments

Survey options:
[Survey Queue](#) [Survey Login](#)
[Survey Notifications](#)
[Upload or download Auto Invitations](#)

Add new instrument:
[Create](#) a new instrument from scratch
[Import](#) a new instrument from the official **REDCap Shared Library**
[Upload](#) instrument ZIP file from another project/user or [external libraries](#)

Library contains instruments submitted by REDCap Consortium members

Return to REDCap

Logged in as **Heather Lansky** (The Ohio State University)

Keyword search: [Search the library](#)

Search options:
 Language:
 Minimum downloads:
 Recent additions:
 Curated by REDLOC?

Shared Library
 Search
Library Metrics
 My Activity
 Institution Activity
 Consortium Activity
REDLOC
 REDLOC Login

1 2 3 >>

Found 55 results matching your search [Didn't find what you were looking for? Suggest a validated instrument for library inclusion](#)

Title	Downloads
▶ Combined Consent & HIPAA Authorization Template	0

Search for "Combined Consent"




Title	Downloads
<p>▼ Combined Consent & HIPAA Authorization Template</p> <p>Details:</p> <p>Institution: The Ohio State University Contact: Heather Lansky Contact email: lansky.8@osu.edu Submitted by: Heather Lansky Description: Consent adapted from template retrieved from ORRP website. Version of consent is current as of 2/1/19 and includes new elements of consent according to 2018 Common Rule updates.</p> <p>Acknowledgement: Adapted from Combined Consent & HIPAA Authorization Template (http://orpp.osu.edu/irb/investigator-guidance/consent/)</p> <p>Terms of use: For use by faculty, staff, and affiliates of The Ohio State University only. Last updated: March 20, 2019</p> <p>View as web page View as PDF Import into my REDCap project</p>	0

Import into project




Survey Settings for eConsent




Data Collection Instruments

Survey options:

-  Survey Queue
-  Survey Login
-  Survey Notifications

Add new instrument:

-  Create a new instrument from scratch
-  Import a new instrument from the official [REDCap Shared](#)
-  Upload instrument ZIP file from another project/user or [ext](#)

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related opti
Consent	43			Choose action ▾	 Survey settings

Scroll through survey settings as desired

Survey Termination Options

e-Consent Framework and PDF Auto-Archiver disabled by default

Use e-Consent Framework and Auto-Archiver when collecting signature

SAVE CHANGES!!

e-Consent Framework
– and –

PDF Auto-Archiver
Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.

Disabled
 Auto-Archiver enabled
 Auto-Archiver + e-Consent Framework [What is the e-Consent Framework?](#)
(includes end-of-survey certification & archival of PDF consent form)

e-Consent Framework Options:
For e-Consent it is sometimes required to include the consenting participant's name (and date of birth in some cases) on the final consent form as extra documentation of their identity. Below you may select fields used to capture that info. You may also enter the current e-Consent version and e-Consent type for this form. The values for the fields below will be automatically inserted into the footer of the PDF consent form that the participant will review at the end the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

Allow e-Consent responses to be edited by users?

e-Consent version: e.g., 4

First name field: in

Last name field: in

Note: If you are using a single field to capture whole name, you may select it for either first/last name above while leaving the other name field unselected.

Optional fields (these are not always necessary for e-Consent):

e-Consent type: e.g., Pediatric

Date of birth field: in

Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page?
Select a field below that serves as a signature field in this survey. It could be a [free-form text field](#), a [signature field](#), or a [number field](#) (e.g., to collect a PIN), and it must be a [Required field](#). If any fields are selected below, then if the participant gets to the last page of the survey where it asks them to certify their responses, if they then choose to click the Previous Page button, it will erase the value of these signature fields, thus forcing them to 'sign' the field(s) again before completing the survey. If you do not want this behavior, do not select any fields below. You may use up to five signature fields.

Signature field #1:

eConsent Framework

- Extra certification page at end of survey: in-line PDF for participant to confirm that all info is correct
- Survey is not complete until certified
- Static copy of responses is stored as PDF in File Repository



Informed Consent to Participant in Research

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

1 / 1

Informed Consent to Participant in Research Page 1 of 1

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title : INSERT TITLE HERE

Principal Investigator: INSERT PI NAME HERE

Sponsor: The Ohio State University

1. Why is this study being done?

09/07/2018 9:06pm Wilma Flintstone,, Version: 090718

REDCap

I certify that all the information in the document above is correct, and I understand that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

<< Previous Page

09/07/2018 9:06pm Wilma Flintstone,, Version: 090718

REDCap

Certification Step


- Participant reviews the consent document
- Has the option to download or print
- Certifies that it is correct and that they understand e-signature
- Opportunity to go back and fix
- Note the timestamp and version on the printed copy

Investigator/Staff Consent

- When using the eConsent Framework, once the survey is complete and submitted, it cannot be changed (a 'normal' survey can be edited after completion if the user has those permissions). But eConsents cannot be edited once submitted.
- For this reason, if your study needs to collect PI and/or research staff signature for consenting it needs to be handled differently than having traditional fields on the form for the PI/researcher.

Recommended Method

- Utilize the eSignature and logging functionality for PI/research staff to sign consent
- Caveat: person signing must have a REDCap account

 Lock/Unlock Records

Users with locking privileges also have access to the E-signature and Locking Mgmt page on the left-hand Applications menu.

[Watch video about locking](#)

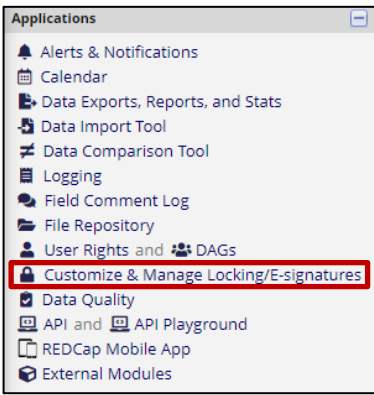
Disabled

Locking / Unlocking

Locking / Unlocking with E-signature authority

[What is an E-signature?](#)



In User Rights, provision permission for user(s) who should be allowed to eSign the consent



Configure eSignatures

Display the Lock option for this instrument?	Data Collection Instrument	Also display E-signature option on instrument?	Lock Record Custom Text	Edit / Remove Custom Text
<input checked="" type="checkbox"/>	Passcode	<input type="checkbox"/>	<input type="text"/> Save	
<input checked="" type="checkbox"/>	Consent	<input checked="" type="checkbox"/>	<input type="text"/> Save	

Check box to display eSignature option

Display the Lock option for this instrument?	Data Collection Instrument	Also display E-signature option on instrument?	Lock Record Custom Text	Edit / Remove Custom Text
<input checked="" type="checkbox"/>	Passcode	<input type="checkbox"/>	<input type="text"/> Save	
<input checked="" type="checkbox"/>	Consent	<input checked="" type="checkbox"/>	I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.	 

Insert statement (per IRB) for PI/staff to attest to. Whatever language is here will appear beside eSignature option

- Once participant has signed the consent, PI/staff can open the consent form and complete the eSignature

Record ID 1 Luke Skywalker

Data Collection Instrument	Status
Passcode	
Consent (survey)	

Click to open

Scroll all the way to the bottom

Text entered on eSignature configuration appears here

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

- Lock
- E-signature [\(What is this?\)](#)

Save & Exit Form

Save & ...

-- Cancel --

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Lock Unlock form

Locked by lansky.8 (Heather Lansky) on 08/06/2020 5:16pm

E-signature [\(What is this?\)](#)

Save & Exit Form Save & ...

-- Cancel --

Record has been locked with who locked it and when. The person locking record does not have to be same as who signs it (although may be easiest).

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Lock Unlock form

Locked by lansky.8 (Heather Lansky) on 08/06/2020 5:16pm

E-signature [\(What is this?\)](#)

Save & Exit Form Save & ...

E-signature: Username/password verification x

Before forms can be locked using an e-signature, you must enter your REDCap username and password so that they may be validated. After three consecutive unsuccessful attempts, you will automatically be logged out of REDCap, thus ending this session.

Username:

Password:

Click box beside e-Signature then click Save and Exit (or Save and Stay, Save & Continue, etc.)

You will be prompted to verify your login

Record ID 1 Luke Skywalker

Data Collection Instrument	Status
Passcode	
Consent (survey)	

Record has been locked and signed


- The first PDF copy in File Repository will only have the participant's e-Signature
- To get a PDF with PI/staff e-Signature, use the "Save Survey PDF to a Field" External Module

Save Survey PDF to a Field - v1.1.2 Discoverable

This module generates a PDF of a survey upon completion and saves it to a REDCap file upload field. It is configured at the project level with source instrument/target field pairs. In the event of save errors, the PDF is sent to a backup email address.

 [View Documentation](#)

PI/staff attestation and information about locking and signature, including timestamp

I voluntarily agree to participate in this study.	<input checked="" type="radio"/> Yes <input type="radio"/> No
Full Name of Subject	Darth Vader
Signature	
E-mail	_____
Date and time	08-06-2020 16:46
Printed name of person authorized to consent for subject (when applicable)	_____
Signature of person authorized to consent for subject (when applicable)	_____
Relationship to the subject	_____
<p>I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.</p> <p>E-signed by lansky.8 (Heather Lansky) on 08/06/2020 4:47pm Locked by lansky.8 (Heather Lansky) on 08/06/2020 4:46pm</p>	



New Process

*Currently only for participants > 18 years who are legally
autonomous
for REDCap v.10*

Options

- Fee – for – service (FFS) or Voucher
 - RIT creates forms and completes setup for the normal FFS fee (\$104/ hour) through either FFS (dept. billing) or a Voucher
 - Currently Available
- DIY
 - TBA: Not available yet; working on a solution with stakeholders

eConsent Template

Overview

- Study staff will document informed consent procedures using the approved COM eConsent REDCap template
- New eConsent template features
 - Consent version tracking and control
 - Contact log tracking
 - Verification using passcode with survey login
 - eConsent framework
 - Multi-Signature Functionality

eConsent Template

Overview

Arm 1: Consent

Arm 2: Consent History

Data Collection Instruments		Survey options:			Add new instrument:		
		Survey Queue	Survey Login		Create	a new instrument from scratch	
		Survey Notifications			Import	a new instrument from the official REDCap Shared Library	
		Upload or download Auto Invitations			Upload	instrument ZIP file from another project/user or external libraries	
Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options		
Contact Info	7		Enable	Choose action			
Contact Log	16		Enable	Choose action			
Consent Step 1	18		Enable	Choose action			
Consent Step 2	9		Enable	Choose action			
Consent Elements	51			Choose action	Survey settings	Automated Invitations	
Unable to Complete	9		Enable	Choose action			
Team Review Signature	7		Enable	Choose action			
Confirm Consent	15		Enable	Choose action			
Final Consent	6			Choose action	Survey settings	Automated Invitations	
Consent History	17		Enable	Choose action			

eConsent Template




Overview: Consent History Arm

Arm 1: Consent Arm 2: Consent History

Record ID	Consent History
<u>1</u>	 +



Repeating Instruments

Consent History	
Consent History (Arm 2: Consent History)	
(3)	
1	 Version: 1, Approval Date: 2021-05-01, Expiration Date: 2021-09-01
2	 Version: 2, Approval Date: 2021-09-01, Expiration Date: 2021-12-12
3	 Version: 3, Approval Date: 2021-12-13, Expiration Date: 2022-05-31
+ Add new	

eConsent Template

Consent History Arm: Consent Repository

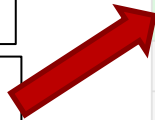
IRB approved consent form as PDF or Word



IRB approval letter for study as PDF or Word



All IRB approved study documents as PDF or Word



Consent History	
INSTRUCTIONS	
Consent Version	<input type="text" value="Version #"/>
Upload Approved Version	Upload file
Approval Date	<input type="text"/> <input type="calendar"/> Today Y-M-D
Expiration Date	<input type="text"/> <input type="calendar"/> Today Y-M-D
Upload IRB Approval Letter	Upload file
Upload IRB Approved Study Documents (.zip file)	Upload file
Protocol Number	<input type="text" value="Protocol #"/>
Are witnesses required?	<input type="radio"/> Yes <input type="radio"/> No If "Yes" is selected, this will trigger spots for witness signatures on the eConsent template reset
Description of Modifications to Consent	
<p>*This box appears after the first instance of the form to include information on why the Consent form was changed*</p>	
Expand	

eConsent Template

Consent History Arm: History Instance Table

Show entries Search:

#	Consent Version	Consent Form - Approved Version Upload	IRB Approval Letter	IRB Approved Documents - Zip File	Approval Date	Expiration Date	Protocol Number	Does the consent require a witness?	Indicate the number of witnesses for consent	Form Status
1	1	Download	Download	Download	2021-05-01	2021-09-01	2021C0099	No (0)		
2	2	Download	Download	Download	2021-09-01	2021-12-12	2021C0099	No (0)		
3	3	Download	Download	Download	2021-12-13	2022-05-31	2021C0099	No (0)		

Showing 1 to 3 of 3 entries Previous Next

[+ Add new](#)


eConsent Template

1 Consent Arm: Contact Information

Complete:

- First & Last Name
- Email (for sending consent)
- Phone Number (for contacting participant)

Contact Info

 Editing existing Record ID 16 Carroll, Amanda



Event Name: **Screening (Arm 1: Consent)**


Record ID 16
To rename the record, see the record action drop-down at top of the [Record Home Page](#).

Participant Contact Info

First Name	<input type="text" value="Amanda"/>	Last Name	<input type="text" value="Carroll"/>
Email Address	<input type="text" value="amanda.carroll2@osumc.edu"/>	Phone Number	<input type="text" value=""/>

Form Status

Complete?  

Lock this instrument?  **Lock**

If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.

eConsent Template

2 Consent Arm: Contact Log Failed Attempt

- If you get any other Contact Outcome other than "Agree to participate and eConsent", click the "Save and Exit the Record" blue button to exit.
- Create a new instance of the form for your next encounter/ contact
 - You need to note in your IRB submission how many times you can contact a participant

Contact Log

Current instance: 1 - Contact #: 1 / _____

Editing existing Record ID 16

Event Name: Initial Consent (Arm 1: Consent)

Record ID 16

Participant Contact Log

INSTRUCTIONS

Participant Contact Info

First Name	Amanda	Last Name	Carroll
Email Address	amanda.carroll2@osumc.edu	Phone Number	[REDACTED]

Contact Log Details

Contact Date	05-23-2022 Today M-D-Y	Contact Outcome
Start Time	2022-05-23 09:33 Now Y-M-D H:M	<input type="radio"/> Agreed to participate and eConsent <input type="radio"/> Spoke to respondent, will recontact <input type="radio"/> Spoke to household member, will recontact <input type="radio"/> Refused to participate <input checked="" type="radio"/> No answer <input type="radio"/> Left voicemail <input type="radio"/> Disconnected, not in service, or busy signal
End Time	2022-05-23 09:40 Now Y-M-D H:M	reset

Next Contact Date 2022-05-24 15:40 Now Y-M-D H:M

Select a date when the study team plans to re-contact the participant. This value will be used in the "Contact Log" report.

Contact Notes

call back tomorrow

Expand

Save and Exit Record

eConsent Template

2

Consent Arm: Contact Log Successful Attempt

- If participant agrees, select "Agreed to Participate and Consent" as Contact Outcome
- Then select "yes" to begin eConsent process
- Then "Click to Save and Go to Next Form". This will take you to form 3 (Consent Step 1)



Contact Log
Current instance: 2 - Contact #: 2 / Agreed to participate and eConsent

Editing existing Record ID 16 (Instance #2)

Event Name: Initial Consent (Arm 1: Consent)

Record ID 16

Participant Contact Log

INSTRUCTIONS

Participant Contact Info

First Name	Amanda	Last Name	Carroll
Email Address	amanda.carroll2@osumc.edu	Phone Number	[REDACTED]

Contact Log Details

Contact Date	05-24-2022 Today M-D-Y	Contact Outcome	<input checked="" type="radio"/> Agreed to participate and eConsent <input type="radio"/> Spoke to respondent, will recontact <input type="radio"/> Spoke to household member, will recontact <input type="radio"/> Refused to participate <input type="radio"/> No answer <input type="radio"/> Left voicemail <input type="radio"/> Disconnected, not in service, or busy signal
Start Time	2022-05-24 15:30 Now Y-M-D H:M		
End Time	2022-05-24 15:41 Now Y-M-D H:M		

Contact Notes

Expand

Begin eConsent Process

Yes
 No

reset

Contact Log History

Show 10 entries Search:

#	Contact Date	Contact Outcome	Next Contact Date	Contact Notes	Form Status
1	2022-05-23	No answer (5)	2022-05-24 15:40	call back tomorrow	<input checked="" type="radio"/>
2	2022-05-24	Agreed to participate and eConsent (1)			<input checked="" type="radio"/>

Showing 1 to 2 of 2 entries Previous 1 Next

[Add new](#)

Click to Save and Go to Next Form

eConsent Template

3 Consent Arm: Consent Step 1

Once the Consent Version is chosen, "Click to Confirm Consent Version"

Consent Step 1

Editing existing Record ID 16

Event Name: Initial Consent (Arm 1: Consent)

Record ID 16

Consent Process

Verify Consent Version to Use

Step 1. Indicate the consent version to send the participant

Consent Version

*Choose Version History

Click to Confirm Consent Version

*The options in the Consent Version drop-down comes from the forms completed in the Consent History Arm

eConsent Template

3 Consent Arm: Consent Step 1 Wrong Consent Version Chosen

The most recent consent version was not chosen from the list, so a **RED** warning box appears informing that the Consent Version was NOT confirmed, and to please check the Consent Version

Consent Step 1

✓ Record ID 17 successfully edited

✎ Editing existing Record ID 17

Event Name: **Initial Consent (Arm 1: Consent)**

Record ID 17

Consent Process

Verify Consent Version to Use

Step 1. Indicate the consent version to send to participant

Consent Version
Version Num: 3 Approval Date: 2021-12-13 Expiration Date: 2022-05-31
✓ Version Num: 2 Approval Date: 2021-09-01 Expiration Date: 2021-12-12
Version Num: 1 Approval Date: 2021-05-01 Expiration Date: 2021-09-01

Click to Confirm Consent Version


Consent Version is NOT Confirmed
Please Check the Correct Version of the Consent is Selected

Form Status

eConsent Template

3 Consent Arm: Consent Step 1 Correct Consent Version Selected

The most recent consent version was chosen from the list, so a **GREEN** box appears informing that the Consent Version was confirmed, and the "Save and Go to Next Form" button appears

 Editing existing Record ID 16

Event Name: **Initial Consent (Arm 1: Consent)**

Record ID 16

Consent Process

Verify Consent Version to Use

Step 1. Indicate the consent version to send the participant

Consent Version

Consent Version is Confirmed
Please Proceed to Send Participant the Consent

Save and Go to Next Form

eConsent Template

4 Consent Arm: Consent Step 2

- * The 6- digit passcode should:
 - Not be part of their phone number
 - Not be part of their birthday
 - Not be part of their SSN
 - Not be easily known by another person
 - Be an easily remembered number

Once the passcode is set with the participant, read the script for verbal permission to send consent via email. Then click "yes"

Do not email the passcode to the participant. This code should be set up over the phone or in person

Consent Step 2

Editing existing Record ID 16

Event Name: Initial Consent (Arm 1: Consent)

Record ID 16

Consent Process

Complete the steps below to begin the eConsent process

Step 2. Record participant passcode

Participant Passcode
 6 characters remaining

Step 3. Obtain verbal permission from participant to send consent via email

SCRIPT:

"We need your permission to send the consent to you using email. Yes No

Do you give permission for the STUDY consent to be sent to your email: amanda.carroll2@osumc.edu? [reset](#)

Form Status

Complete?

eConsent Template

4 Consent Arm: Consent Step 2

Once everything is complete, the blue "Click to Save and Exit Form" button will appear.

This will take you back out to the participant's record

Consent Step 2

Editing existing Record ID 16

Event Name: **Initial Consent (Arm 1: Consent)**

Record ID 16

Consent Process

Complete the steps below to begin the eConsent process

Step 2. Record participant passcode

Participant Passcode 0 characters remaining

Step 3. Obtain verbal permission from participant to send consent via email

SCRIPT:

"We need your permission to send the consent to you using email.

Do you give permission for the STUDY consent to be sent to your email:
amanda.carroll2@osumc.edu?"

Yes
 No

reset

Click to Save and Exit Form


eConsent Template

5 *Consent Arm: Consent Elements*

- Consent elements (the actual consent form) will be emailed to the participant automatically after Consent Step 2 is complete
- Do NOT open the Consent Elements bubble/ form
- If you need to review the Consent Form with the participant over the phone, have a paper copy on hand

eConsent Template

5 Consent Arm: Consent Elements

 **THE OHIO STATE UNIVERSITY** Resize font: [icon] [icon]

Research Consent & Authorization Form

Page 9 of 13

PARTICIPANT

CONSENT & AUTHORIZATION

IRB Protocol Number: 2021C0099
IRB Approval date: 2021-12-13
Version: 3

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.



I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form.

Link to Download Copy of Informed Consent


Attachment: [StudyName-Consent-Authorization-v3.pdf](#) (0.26 MB)

Printed Name of Participant
* must provide value

Signature of participant [Add signature](#)
* must provide value

Date and time   **Now** M-D-Y:H:MM
* must provide value

[<< Previous Page](#) [Next Page >>](#)

 **THE OHIO STATE UNIVERSITY** Resize font: [icon] [icon]

Research Consent & Authorization Form

Page 13 of 13

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

1 / 9 | - 78% + | [icon] [icon] [icon] [icon] [icon]

Research Consent & Authorization Form Page 1

CONSENT & AUTHORIZATION IRB Protocol Number: 2021C0099
IRB Approval date: 2021/12/13
Version: 3.0

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:

I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

[<< Previous Page](#) [Submit](#)

eConsent Template


6 Consent Arm: Team Review Signature

This form is to send the Consent Form to either the Study Staff to add their signatures

- Should be whomever is completing the consent form with the participant

Once filled out, hit the button to "Send to Study Team" and the blue button will appear to "Save and Exit Form"

Team Review Signature

 Editing existing Record ID 16

Event Name: **Initial Consent (Arm 1: Consent)**

Record ID 16



PI/Study Team: Consent Review and Signature

Provide the full name and email address of the PI or Study Team Member who will be reviewing and signing the participant consent form, and indicate the eConsent is ready to send for review and signature.

PI/Study Team Member Full Name	<input type="text" value="Amanda Carroll 2"/>
PI/Study Team Email	<input type="text" value="amanda.carroll2@osumc.edu"/>
Send eConsent for Review and Signature	<input checked="" type="radio"/> Send to PI/Study Team reset

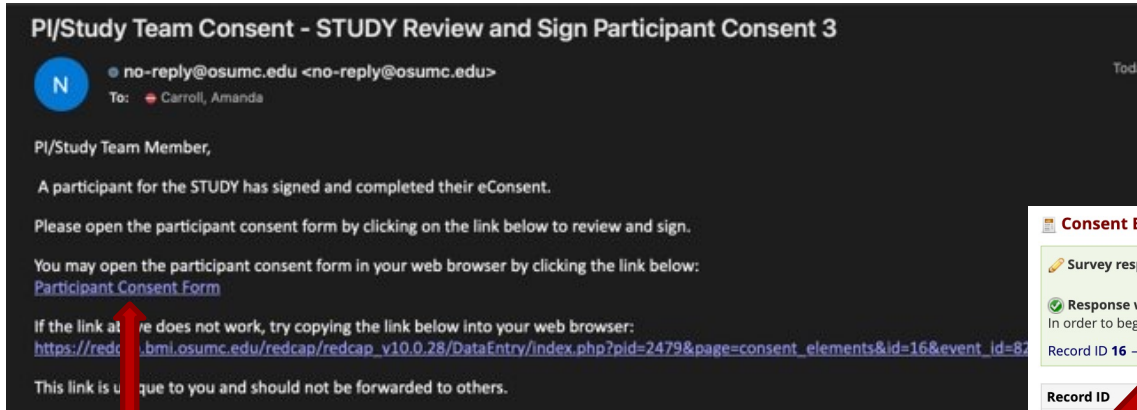
[Click to Save and Exit Form](#)

Form Status

Complete?   Incomplete ▾

eConsent Template

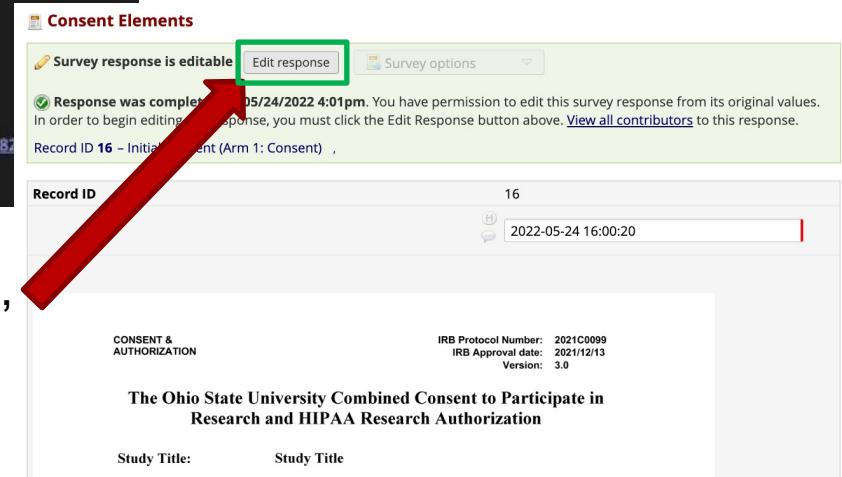
6 Consent Arm: Team Review Signature



With a link that will take them into the project (data entry mode)

Once in the project, click the "Edit Response" button

The email to the Team Member will look something like this




eConsent Template

6

Consent Arm: Team Review Signature

Consent Elements

 Survey response is editable (now editing) 

 Response was completed on 05/24/2022 4:01pm. You have permission to edit this survey response from its original values. [View all contributors](#) to this response.

Record ID 16 – Initial Consent (Arm 1: Consent) ,

Once editable, the research staff can provide their name, signature, and date time

Once signed, mark complete and Save and Exit

INVESTIGATOR/RESEARCH STAFF

CONSENT & AUTHORIZATION

IRB Protocol Number: 2021C0099
IRB Approval date: 2021-12-13
Version: 3

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed Name of Person Obtaining Consent

* must provide value

Signature of Person Obtaining Consent:

* must provide value

 [Add signature](#)

Date Time

* must provide value

   Now M-D-Y H:M

Form Status

Complete?

Lock this instrument?

  Lock

Save & Exit Form

Save & Go To Next Form 

eConsent Template

7 Consent Arm: Confirm Consent

Click "yes" to confirm participant consent is complete



Click "yes" to confirm Team Member consent complete



Check that Consent Version is Confirmed and box is green



Click "yes" to save a copy of consent with ALL signatures



Confirm Consent

Editing existing Record ID 16

Event Name: Initial Consent (Arm 1: Consent)

Record ID 16

Confirm Consent Complete

Review the information provided and confirm necessary signatures were obtained.

Participant Signed Consent

Participant Name	Amanda Carroll
Participant Signature ID	148582
Date/Time Participant Signed Consent	05-24-2022 16:01:35
Confirm Participant Consent Complete	<input checked="" type="radio"/> Yes <input type="radio"/> No reset

PI Signed Consent

PI/Study Team Member Name	Amanda Carroll 2
PI/Study Team Member Signature ID	148584
Date/Time PI/Study Team Member Signed Consent	05-24-2022 16:06
Confirm PI Consent Complete	<input checked="" type="radio"/> Yes <input type="radio"/> No reset

Consent Version is Confirmed

Please Proceed to Send Participant the Consent

Save Signed Consent

Save copy of consent with all signatures	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
--	--

Click to Save and Go to Next Form

Form Status

eConsent Template

8 Consent Arm: Final Consent

Click here or here
to download the
consent form

After scrolling through and making sure both signatures appear, click "yes" to verify and "yes" to send a copy to the participant for their personal record

Confirm Signed Consent Complete

Review the signed copy of the informed consent and verify it is complete.

Please Click on the Link to Download a Signed Copy of Informed Consent

file_downlo... 10 / 11 | - 64% + | [Icons]

PARTICIPANT
CONSENT & AUTHORIZATION
IRB Protocol Number: 2021C0099
IRB Approval date: 2021-12-13
Version: 3

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form.

Link to Download Copy of Informed Consent
[Attachment: "StudyName-Consent-Authorization-v3.pdf"]

Printed Name of Participant Amanda Carroll
Signature of participant

Date and time 05-24-2022 16:01:35

[pid2479_formConsent_Eleme...60717.pdf \(1.81 MB\)](#)

[Upload new version](#) or [Remove file](#) or [Send-It](#)

Send Signed Consent To Participant

Did you review the signed PDF and confirm all signatures are saved?	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Send copy of signed consent form to participant	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset

Click to Save and Exit Form

Form Status

eConsent Template

File Repository of PDF

File Repository

This page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.

[User Files](#)[Data Export Files](#)[PDF Survey Archive](#)[Upload New File](#)

Displayed below are PDF files that have been automatically captured and stored by the PDF Auto-Archiver setting, which has been enabled by one or more surveys on their Survey Settings page. Only users with 'Full data set' data export privileges will be able to download the archived files. Note: The PDFs below were archived when a participant completes a survey, which means they might be different from other downloadable PDFs in the project that are generated on demand using the current data.

Show entries

Survey Completion Time	Record	Survey	Event	Repeat Instance	Identifier (Name, DOB)	Version	Type	Download
05/24/2022 4:07pm	16 Carroll, Amanda	STUDY - Signed Consent	Initial Consent (Arm 1: Consent)		'Multi Signature Consent'	NULL	NULL	
05/24/2022 4:01pm	16 Carroll, Amanda	Research Consent & Authorization Form	Initial Consent (Arm 1: Consent)			3		

A copy of the final consent with BOTH signatures



A copy of the consent with ONLY the participant signature



eConsent

Notes

- The new REDCap eConsent template should be a SEPARATE project from the rest of your forms
 - AKA: submit a project request form for both eConsent and your "normal" project
 - You could also include a screener in the eConsent template project
- If you want to use the new template but don't want to pay for RIT to build the rest of your forms, this is ok! We will work with your team and their needs

eConsent

NEW eConsent Template Request Process

1. Submit a new REDCap project request form: <http://go.osu.edu/newprojectrequest>
2. Schedule an eConsent consultation & send forms
3. RIT EDC will send a quote
 - Apply for voucher if applicable
4. REDCap Administrator will build and configure the REDCap project based on the IRB approved methods for the study
5. Meet with study team to review eConsent procedures, setup and finalize settings
6. The eConsent project will be deployed once IRB approval has been obtained
 - IRB approved documents must be uploaded, and consent history related information documented in the REDCap eConsent project

REDCap Blog

<https://u.osu.edu/redcap/>

[HOME](#)

KNOWLEDGE BASE

FAQ, Troubleshooting, “How do I?”

GETTING AN ACCOUNT

Getting an account – [New User Request](#) / [Background Check](#)

REQUEST A NEW
PROJECT

Request a new REDCap project (<http://go.osu.edu/newprojectrequest>)

REDCAP URLS

REDCap URLs ([PHI](#) and [NonPHI](#))

TRAINING AND EVENTS

[View training schedule and registration links](#)

SCHEDULE A
CONSULTATION

[Schedule a consultation](#)

REGULATORY ISSUES ▶

[IRB Boilerplate](#), [Citing REDCap in publications](#)

REDCAP CUSTOMER
FEEDBACK



Thank You

RIT
REDCap Administrative Team
ccts-informatics@osumc.edu