eSignature for Research Informed Consent

Ben Crawford
Where to begin?

Signature or Acknowledgement?

Am I using an Approved System? (u.osu.edu/esigforinformedconsent)

Is my electronic signature method approved?
Electronic Signatures for Informed Consents Website

https://u.osu.edu/esigforinformedconsent/
What if my methods are not approved?
What if my system is not approved?

1. OCIO audits system against electronic signature policy.
2. OCIO submits audit for approval.
3. OCIO contacts IRB with approval or denial.
eSignature for Consents Approval Process

Study Coordinator

New System Not Approved

Approved System Service Owners

New System Service Owner

Follows Approved Method

IRB

Approved System New Method Amendment Document Created

New System Approval Document Created

OCIO

Policy Owners
Thank You!

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Signet
What is Signet?

- Office of Research supported consent management application built for The Ohio State University researchers.
- Built to be as simple and streamlined as possible
Buck-IRB Integration

• Automatically restricts access for viewing, editing and collecting consent forms based on the current study team.

• Easy upload of a clean consent copy to your protocol’s submission form
3 Ways to Sign

• In person with an investigator
  • In a clinic, or in the field

• Unique participant link + access code
  • Working remotely with participants across the world

• Anonymous attestation
  • Integrate as a step in a Qualtrics form with a wider reach
  • Not legally binding
Collect signatures, start new forms, or revise existing forms from your home workspace

Download clean copies for Buck-IRB

Access participant information and download signed copies
 Audit logs with every signed form
  - Who signed it and how
  - Who downloaded a copy
Creating a Form

Simple 3-step process

1. Pick from one of the ORRP approved templates
2. Fill out your form’s title and protocol
3. Use a Word-like editor to make any changes to the template before publishing
Signing a Form

- Signature capture is done within the form for both participants and research staff
- Research staff may sign at a later date if working with a remote participant
Demo
Interested in Joining the Pilot?
Let us know at econsentforresearch@osu.edu

Thank You!
Office of Research Information Systems
Chase McManning (Sr. Developer)
Obtaining Informed Consent Using REDCap
What is REDCap

- Acronym for Research Electronic Data Capture
- Originated from the Vanderbilt Institute for Clinical and Translational Research
- Secure, web-based data collection system
- Data are stored securely, on OSU premises
- Access rights granted on per-individual basis, can be configured to allow identified or de-identified data set
- Built-in audit trail of what was done and when (valuable for IRB, DSMB, etc.)
To Sign or Not to Sign?

- Signature is not necessarily required
- IRB will make the determination
- Usually only for studies that are *more than minimal risk*
Obtaining Signature - Approved Methods

- In person (e.g., in clinic)
- 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
- Using a piece of information known to the participant which is also stored in REDCap. However, using PHI/PII as a passcode is the last resort
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 signature box, can be deleted if not needed
Library contains instruments submitted by REDCap Consortium members

Search for “Combined Consent”

Import into project
Adding a Signature Field

- If not using the template, a signature field can be added to any REDCap form
Survey Settings for eConsent

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Fields</th>
<th>View PDF</th>
<th>Enabled as survey</th>
<th>Instrument actions</th>
<th>Survey-related options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent</td>
<td>43</td>
<td></td>
<td></td>
<td>Choose action</td>
<td>Survey settings</td>
</tr>
</tbody>
</table>
Survey Termination Options:

- **Auto-continue to next survey**: Automatically start the next survey instrument after finishing this survey.
- **Redirect to a URL**: Redirect to a webpage when the survey is completed.
- **Survey Completion Text**: Displayed after survey completion as thank you text or acknowledgement text.

PDF Auto-Archiver disabled by default:

Use Auto-Archiver + e-Consent Framework when collecting signature.

Save confirmation email (optional)?

(Email the respondent when they complete the survey)

Save Changes!!
Auto-Archiver and eConsent Framework

- Allows enhanced management of survey when it is an informed consent document

- Identify the version
- Select name field
- Optional type and DOB
eConsent Framework

- Extra certification page at end of survey: inline 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
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
PDF Archive in File Repository

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.

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 are 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 10 entries Displaying

<table>
<thead>
<tr>
<th>Survey Completion Time</th>
<th>Record</th>
<th>Survey</th>
<th>Identifier (Name, DOB)</th>
<th>IP Address</th>
<th>Version</th>
<th>Type</th>
<th>Download</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/07/2018 9:09pm</td>
<td>1</td>
<td>Informed Consent to Participate in Research</td>
<td>Wilma Flintstone,</td>
<td>10.39.155.105</td>
<td>090718</td>
<td>PDF</td>
<td></td>
</tr>
</tbody>
</table>
Using a Passcode

- In addition to previous steps, a passcode variable must be added to a form other than the consent document.
- The passcode variable must be populated for the participant before distributing the link to the informed consent survey.
- Enable the Survey Login Function.
Survey Login disabled by default

Select up to 4 fields to be used as a passcode
Usually one is sufficient
Set minimum required fields

Optional error message

Number of failed login attempts
Thank You

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Demo Link

Using REDCap for eConsent

Kelly Dunsky, MS, CCRC
Clinical Research Manager
Clinical Trials Management Organization
Study Overview

Principal Investigator: Benjamin Kaffenberger, MD
Division of Dermatology

Study Title: Patient Reported Outcomes and Survey Instruments in Dermatology

Study Procedures:
• Survey is administered to participants in the Dermatology Clinics via tablet
• Survey and electronic consent are completed through REDCap
• In addition to the survey responses, clinical data elements are collected from the EMR and entered into REDCap
Study Procedures

• IT assisted with loading a link to the REDCap survey onto the homepage of the study tablets

• Qualifying participants are approached during dermatology clinic visits

• Study staff provide the tablet to the participant, review the ICF with them, and witness the participant electronically signing the consent

• Participant is able to complete the survey during downtime in their visit

• Coordinators review the REDCap database and add in additional study data collected from EMR
It was a good idea, but...

- **Idea:** Secure tablets in clinic waiting area for all patients to complete survey.
  - **Goal:** increase enrollment.
  - **Challenge:** building in screening questions to REDCap survey
  - **Challenge:** Dual authentication

- **Idea:** Utilize ResearchMatch.org for recruitment
  - **Goal:** increase enrollment
  - **Challenge:** Dual authentication
  - **Challenge:** No clinical data
Lesson Learned

• Providing copies of the ICF to participants was challenging—sometimes difficult to catch them before they left the clinic

• Solution:
  • Build question into REDCap asking participants to identify if they would like to receive a copy of the consent via email or mail
  • Participants enter their email or mailing address
  • Coordinating staff check survey results weekly and provide participants with copy of ICF
  • Letter was IRB approved to accompany copy of ICF
Other Operational Considerations

• Record maintenance:
  • Participants who open the survey link, but do not complete consent still show up as an incomplete record. These must be periodically deleted.
  • Incomplete surveys

• Updated ICFs:
  • Must ensure that the updated ICF is deployed in REDCap upon receiving IRB approval
Thank you!