



AUGUST 2022 V2.0

REDCAP
WVU IRB
ELECTRONIC INFORMED CONSENT
START GUIDE
WVU OHRP

REDCap Electronic Informed Consent (eIC)

- ❖ Use these instructions ONLY when WVU is the IRB of Record.
- ❖ REDCap eConsent forms do not use an eSignature field. The REDCap eConsent Framework captures the agreement to participate as a digital signature by asking the participant/LAR to check a box containing text related to the agreement. The eConsent Framework (a feature in REDCap) locks the record and provides other information and technical features required for federal regulations and institutional policy. For additional information, please refer to the documentation in REDCap. Note that the eConsent Framework meets FDA certification requirements. **When discussing consent with participants/LARs, be sure to use the word "signature" carefully as the participant/LAR will not SIGN the form using the traditional method of signature.**
- ❖ If you would like assistance for eConsent before you submit the protocol, contact [WVU OHRP](#) for an eIC Consultation before you begin or visit the [WVU OHRP website](#).

1. Access REDCap

Log in to <https://redcaplive.wvctsi.org/redcap/> using your WVU credentials.

If you do not already have a REDCap account, follow the instructions listed on [this page](#) to submit a REDCap account request through iLabs.

2. Download the eIC Submission Worksheet

The WVU IRBs require an eIC Submission Worksheet for all full board protocols and for expedited, exempt, flex, and NHSR when PHI is involved to facilitate protocol review and approval. The worksheet includes questions regarding how eIC will be used for consenting participants/LARs in-person, remotely, or both. Completing the worksheet should eliminate the need for time-consuming revisions.

Click [here](#) to access to WVU OHRP website Forms page. Scroll down to the Electronic Informed Consent Submission Worksheet section of the page.

3. Locate the WVU IRB Approved eTemplates

The eTemplates are available in the REDCap Library.

The eTemplates can be customized; however, **the WVU IRB must approve any change to the eTemplate**. Modifications should be clearly explained in the *eIC Submission Worksheet*.

To create an eTemplate :

1. Click the "+ **New Project**" tab at the top of the screen
2. Select "**Use a template (choose one below)**"
3. Choose the applicable eConsent template based on your research project.

4. Ensure your project title includes the PI last name and WVU+kc protocol number as well as the full project title. Example: Smith 1234528591 Title of Study Here

4. Verification of Identity (Required for FDA regulated research)

FDA guidance for eIC requires the consenting researcher to verify the identity of the person who will sign the consent form from a remote location. The standard method is to view a formal ID while on the required HSC Zoom video session. If this is not possible, the researcher can use the three identity verification questions. The participant/LAR is asked to enter their first name, last name, and birth month. The participant/LAR is requested to enter their answers to the questions as a "login" when they click on the link to open the consent form.

5. Initial Protocol Submission

NOTE: All eConsent forms presented to a prospective participant/LAR must be included in the protocol submission.

The standard content provided with the eTemplates, including survey questions, email message text, subject lines, messages to the prospective participant, **cannot** be changed unless approved by the WVU IRB. Only Logos approved by University Relations can be inserted into the eTemplates.

Modifications could include additional questions, embedded videos, or links to websites. Note that all electronic materials that will be presented to the participant/LAR must be submitted to the WVU IRB (**the link (url) and a PDF of the contents of the electronic material**).

NOTE: After customization, the eTemplate is considered an eConsent Form and is in a draft state similar to the Informed Consent Form. The draft contains a "placeholder" PDF for ADA compliance and a "placeholder" image file. The PDF and the image file will be replaced after WVU IRB approval.

Be sure to describe any requested changes to standards in the *eIC Submission Worksheet*.

1. Modify the eTemplate to include the PI name and contact information and activate automated survey invitations for the consent form.

The WVU IRB requires that a researcher(s) be designated to monitor returned responses. When completed forms are returned to WVU through REDCap, email messages are sent to the addresses included in the Survey Notification option.

Click "Designer" within the Project Home and Design menu section

- Click "Survey Notification" within the Survey Options section
- Select the researchers to be notified by selecting their email address in the drop-down list.

OHRP-e01 MMR\OMR with Signature

Project Home | Project Setup | **Online Designer** | Data Dictionary | Codebook

Create snapshot of instruments | VIDEO: How to use this page
Last snapshot: 12/17/2020 8:45pm

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.

Survey options: Survey Queue | Survey Login

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

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
OHRP-e07 Permission to Use Email	16			Choose action	Survey settings Automated Invitations
OHRP-e01 MMR/OMR With HIPAA	22			Choose action	Survey settings Automated Invitations

Ensure Automated Invitations are Activated for the eConsent. Click the red "automated invitations" button next to the consent form instrument and click "active" under step 4.

Define Conditions for Automated Survey Invitations (ASI)

Survey title: WVU Informed Consent Form

STEP 1: Compose message

From: WVU Research [hsr survey@hsc.wvu.edu] (select any project user to be the 'Sender')

To: [All participants who meet the conditions defined]

Subject: Message From WVU

Send test email

Paragraph [B I U] [List icons] [Link icon] [Undo/Redo icons]

Please click on the link below to open the informed consent form.
[survey-link]
If the link does not work, cut and paste the url below into the address bar of your browser.
[survey-url]
Please contact the Principal Investigator if you need assistance.

NOTE: You may modify or remove any text you wish in the Compose Message text box above. Make sure you include either [survey-link] or [survey-url] in the text or else the participant will not have a way to take the survey.

[How to use Piping in the survey invitation](#)

Specify conditions for sending invitations:

When the following survey is completed:
"WVU Email Disclosure Form"

AND

When the following logic becomes true:
[email_permission_v2]=1'
(e.g., [age] > 30 and [sex] = "1")

[How do I use special functions?](#)

Test logic with a record: --select record--

Ensure logic is still true before sending invitation? [?]
[How to use 'stop logic' to disable an automated invite](#)

STEP 3: When to send invitations AFTER conditions are met

Send immediately

Send on next --select day-- at time [] H:M

Send the invitation after time lapse of [] days [] hours [] minutes

Send at exact date/time: [] M/D/Y H:M

OPTIONAL: Enable reminders

Re-send invitation as a reminder if participant has not responded by a specified time?

STEP 4: Activated?

Activate these automated invitations? In order for automated survey invitations to be sent using these specified conditions, it must be set to Active. You may make them Not Active (and vice versa) at any point in the future. NOTICE: Setting it to 'Not Active' will not prevent any invitations from sending that have already been scheduled, in which case they instead be deleted manually.

Active Not Active

Save Save & Copy to... Cancel

2. Obtain the link (url) for the eConsent Form to include in the *eIC Submission Worksheet*:

Select SURVEY DISTRIBUTION TOOLS from the menu to the LEFT of the screen.

Click on the COPY icon (see red arrow) and PASTE the link in WVU+kc.

Survey Distribution Tools

Public Survey Link

Participant List

Survey Invitation Log

Using a public survey link is the simplest and fastest way to collect responses for your survey. You may obtain the survey link below to email it to your participants. Responses will be collected anonymously (unless the survey contains questions asking for identifying data from the participant). **NOTE:** Since this method uses a single survey link for all participants, it allows for the possibility of participants taking the survey multiple times, which may be necessary in some cases.

To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey.

Public Survey URL: 

Link Actions

Open public survey

Open public survey + Log out

Send me URL via email

Survey Access Code or QR Code

Link Customizations

Get Short Survey Link

Create Custom Survey Link

Get Embed Code

- To obtain a PDF of the eConsent Form to attach in the ATTACHMENTS tab of WVU+kc:
 - Select the ONLINE DESIGNER TAB from the menu at the top of the screen.
 - Click on the Adobe PDF icon, a file will be downloaded.
 - Attach the file to the protocol submission ATTACHMENTS tab in WVU+kc.

Form Name	Fields	View PDF	Enabled
Verification Question and Answer Form	15		
Consent Form	15		
Obtaining Person's Signature - Not a Survey Form	2		Enable

6. Determining and Configuring Distribution Methods.

NOTE: Links (urls) cannot be sent using WVU, HSC, or WVU Medicine email systems; all electronic information consent materials MUST be sent within REDCap. The REDCAP Participant List should be used to send eConsent forms.

There are multiple options for distribution depending on the research project requirements. Please refer to the REDCap documentation and discuss distribution methods with the [WVU REDCap Administrator](#). Describe the distribution method in the *eIC Submission Worksheet*.

In-Person Consent

When using eConsent forms in-person, an email can be used to provide the link (via the participant distribution list function in REDCap) or manually on a device provided by the study team (no email needed).

Remote Consent

The participant distribution list function in REDCap must be used to email the survey to the participant.

7. After WVU IRB Approval:

After the WVU IRB approves the protocol, the Informed Consent Document must be attached to the eConsent Form as a PDF. Each page must be uploaded as an image file (replacing the placeholder pages).

1. Attach the approved watermarked PDF of the Informed Consent Form or Cover Letter for ADA Compliance

Replace the "placeholder" document by uploading and attaching the PDF of the approved and watermarked informed consent document. The PDF is required to enable the document to be read by a screen reader. The document in the electronic consent form is an image and cannot be read. This PDF is for review only; it should not be signed. **The signature is obtained electronically using REDCap through the REDCap eConsent Framework – Note that this is not an eSignature where the person uses a mouse, finger, or stylus to "draw" a signature; it is a checkbox.**

2. Upload the image files for each page of the IRB Approved and Watermarked Informed Consent Form.

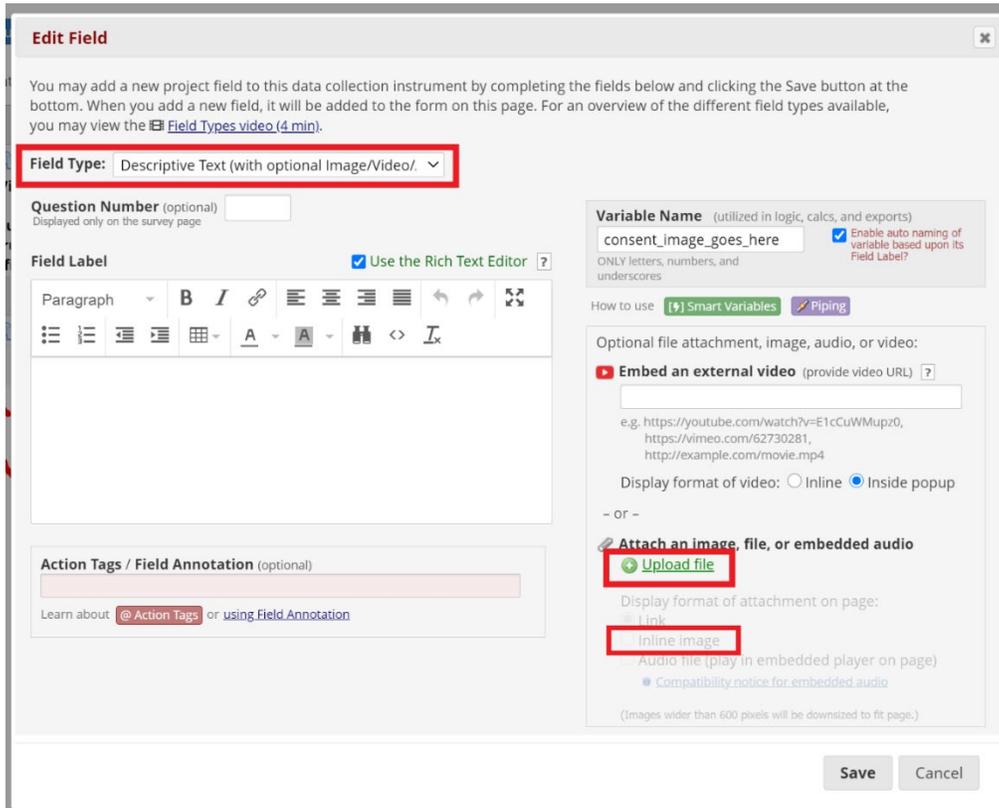
After completing this step, the Informed Consent Document will be visible within the eConsent Form as an image file. Including the document facilitates the discussion between the consenting person and the prospective participant/LAR. The page breaks to allow for a pause after each page to ensure understanding (federal and institutional requirements).

The images also enable REDCap to provide the participant/LAR with a complete PDF of the signed informed consent document (the eSignature and the approved/watermarked Informed

Consent Document); without the images, the PDF would only include the answers to the REDCap survey fields.

To display your consent form within the eTemplate survey and to facilitate a complete PDF of the consent form with eSignatures:

1. Replace the tutorial image with a high-resolution image approved informed consent form.
2. Create the image by exporting a PDF of the informed consent form as a .jpg file or PNG using a preferred PDF editor. Each page will be a separate file.
3. To upload the images to the survey form:
 - Add a field or edit the existing tutorial image
 - Set the Field Type to "Descriptive Text (with optional Image/Video/Audio/File Attachment)"
 - Select "Upload file," then choose the file
 - Select "Inline Image" for the "Display format of attachment on page."



The screenshot shows the 'Edit Field' interface in REDCap. The 'Field Type' dropdown is highlighted with a red box and set to 'Descriptive Text (with optional Image/Video/Audio/File Attachment)'. The 'Variable Name' field contains 'consent_image_goes_here'. The 'Attach an image, file, or embedded audio' section has 'Upload file' selected with a red box. The 'Display format of attachment on page' section has 'Inline image' selected with a red box. The 'Save' and 'Cancel' buttons are at the bottom right.

4. Add a page break (regulatory requirement) after each image.
 - Add a new field between two images
 - Set Field Type to "Begin New Section (with optional text)"
 - Click Save

Add New Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Begin New Section (with optional text)

Field Label Use the Rich Text Editor ?

Save Cancel

Survey Distribution Tools

Public Survey Link **Participant List** Survey Invitation Log

The Participant List option allows you to **send a customized email** to anyone in your list and **track who responds to your survey**. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). Note: All survey responses collected are considered anonymous unless you 1) are using Participant Identifiers or 2) have enabled the designated email field for invitations. [More details](#)

Participant List belonging to [Initial survey] "WVU Research Email Use Agreement" Remove all participants

Displaying --ALL-- of 0 **Add participants** Compose Survey Invitations Export list

Email	Record	Participant Identifier (optional)	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
No participants have been added							

8. Create a Participant List

Create a Participant list.

- Click "Survey Distribution Tools" in the Data Collection section of the left-hand menu
- Click the "Participant List" tab towards the top of the screen
- Select the "Add participants" button
- Add the emails of the participants, **one per line**
- Click "Add participants."
- Click "Compose Survey Invitations"
- Compose the email invitation (**this should be an IRB-approved message**) and select the participants to receive the email invitation within the participant list checkbox, then click "Send Invitations."
- You can add to the list as participant join.

9. Send the eConsent Forms

Using the approved distribution method, distribute the eConsent forms to remote and in-person prospective participants/LARs.

10. Access and Manage Responses

Email messages will be sent to notify of returned responses to the email addresses entered in Survey Notifications

To view the eConsent forms that have been submitted by participants, select "Record Status Dashboard" in the Data Collection section of the left-hand menu. This screen will display a table listing all existing survey responses.

REDCap
OHRP-e01 MMR\OMR with Signature

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard] [Create custom dashboard](#)

Displaying record [] of 0 records ALL (0) records per page

+ Add new record

Displaying: Instrument status only | [Lock status only](#) | [All status types](#)

Record ID	OHRP-e07 Permission to Use Email	OHRP-e01 MMR/OMR With HIPAA	Consenting Person
No records exist yet			

Legend for status icons:

- Incomplete
- Incomplete (no data saved)
- Unverified
- Partial Survey Response
- Complete
- Completed Survey Response

11. Consenting Person Signature (Required for MMR)

For MMR protocols, the Consenting Person's eSignature is required. For OMR with PHI, this is not required but is included in the REDCap project for the eTemplate (but can be deleted). Note that the signature in this step IS an eSignature provided by a mouse, finger, or stylus.

When a participant has returned a form, the consenting person must sign the eConsent Form using the "Consenting Person" instrument included with the REDCap eTemplate project. The consenting person will navigate to the Record Status Dashboard and select the status icon for the appropriate Record ID.

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Legend for status icons:

- Incomplete
- Incomplete (no data saved) ?
- Unverified
- Partial Survey Response
- Complete
- Completed Survey Response

Record ID	OHRP-e07 Permission to Use Email	OHRP-e01 MMR\OMR With HIPAA	Consenting Person
1			

The consenting person will complete the two fields, Consenting Person's Full Name and Consenting Person's Signature.

Consenting Person

Editing existing Record ID 1

Record ID: 1

Consenting Person's Full Name:

Consenting Person's Signature: [Add signature](#)

Form Status

Complete?:

Lock this record for this form? Lock

if locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

Buttons: Save & Exit Form, Save & ..., -- Cancel --

12. Send the Fully Executed eConsent Form to the Participant or LAR.

If your study is required to comply with GCP-ICH, the fully executed copy containing the participant/LAR eSignature and the Consenting Person's signature must be sent to the person who signed the Form.

When the consenting person has signed the returned eConsent, a PDF can be sent via REDCap SEND-IT to the participant/LAR. REDCap Send-It is a secure data transfer application for sending and receiving documents. Send-It can also be used to transmit eConsent forms for OMR research.

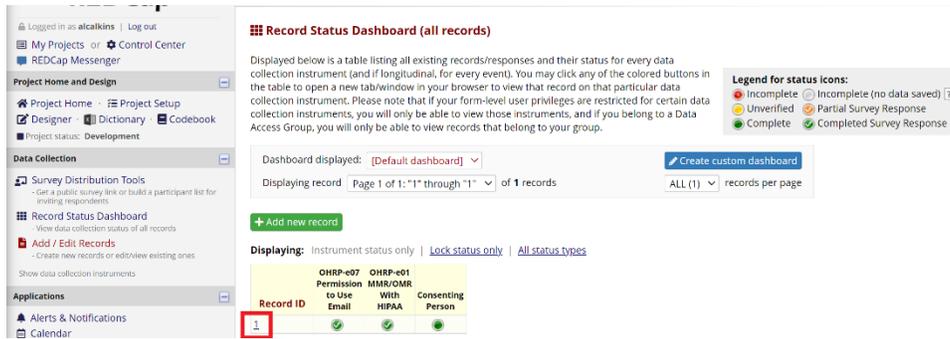
Note: The SEND-IT feature can also be used to send the consent document to the participant if they fail to download their signed copy after they complete the form.

Emailing signed consent forms as attachments using an institutional email address is not permitted by the institution. All consent information must be transmitted using REDCap.

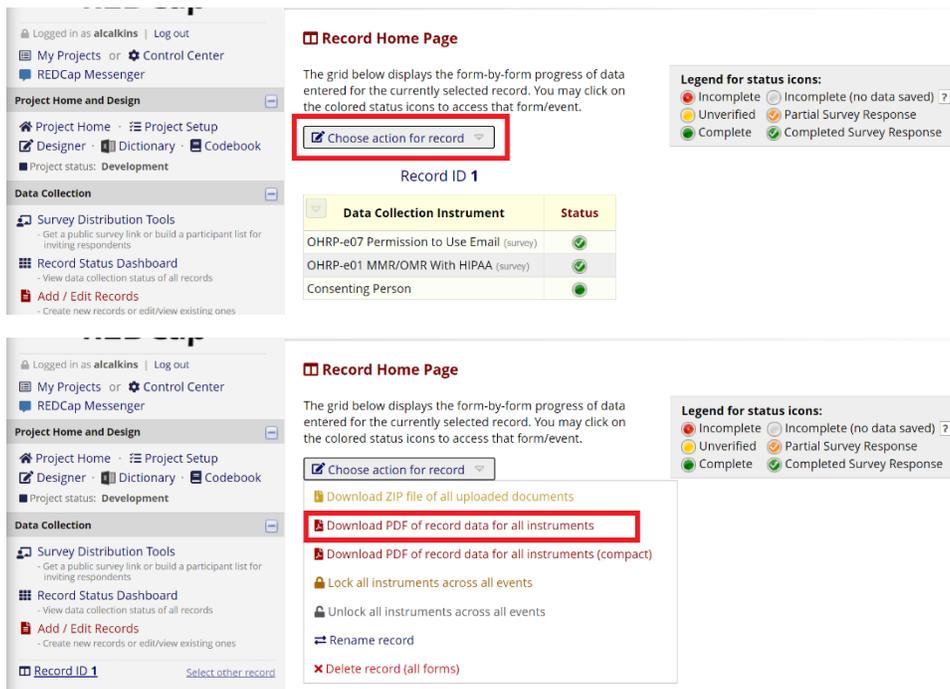
REDCAP SEND-IT:

1. Download the PDF of the fully executed eConsent Form:

- Select the Record ID for the appropriate record from the Record Status Dashboard

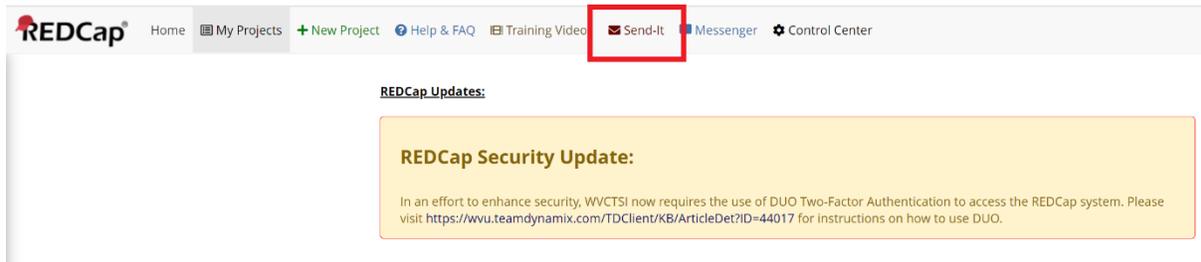


- Navigate to the "Choose action for record" drop-down and select "Download PDF of record data for all instruments."



2. Send the PDF through REDCap Send-It:

- Navigate to the main "My Projects" REDCap page
- Select the "Send-It" tab at the top of the screen



- Fill out the Form and specify to whom you wish to send the file
- **Set the expiration to 14 days – REQUIRED; the WVU IRB must approve changes**
- Check the box for "Receive confirmation?"
- Click "Send It!"

Send-It

Send-It is a secure data transfer application that allows you to upload a file (up to 32 MB in size) and then allow multiple recipients to download the file in a secure manner. Each recipient will receive an email containing a unique download URL, along with a second follow-up email with the password (for greater security) for downloading the file. The file will be stored securely and then later removed from the server after the specified expiration date. Send-It is the perfect solution for anyone wanting to send files that are too large for email attachments or that contain sensitive data.

Instructions for using Send-It:

Fill out the form below to specify to whom you wish to send the file, as well as other custom information and settings. Each email address you enter below will receive a message stating that a file is available for download. The email will include a unique link and password, which the recipient will use to navigate to the webpage for downloading the file to their computer. If the file is very large, it may take several moments to upload, so please allow it to continue to upload until it notifies you of its completion.

From:

To:

(recipient emails)

Separate email addresses with commas, semi-colons, or line breaks

Email subject:

(optional)

Email message:

(optional)

Expiration: Specify the time after which the file will no longer be accessible for download

Select a file: No file chosen (Max file size: 32 MB)

Receive confirmation?
Get an email notification informing you when your file has been downloaded by each recipient.

13. Submitting Revisions to the WVU IRB

Submitting modifications and requested revisions to the WVU IRB is the same process for all other modifications and revisions. Please see the applicable REDCap guides for replacing your consent document in REDCap to ensure you do not lose any data previously collected.