

Setting up e-Consent for an IRB-Approved Study in REDCap

We hope these instructions will make your setup process as straightforward as possible. If there is anything that is not clear, please help the next person out by sending us feedback so we can improve these instructions.

For improvement ideas or questions, email REDCap@gwu.edu

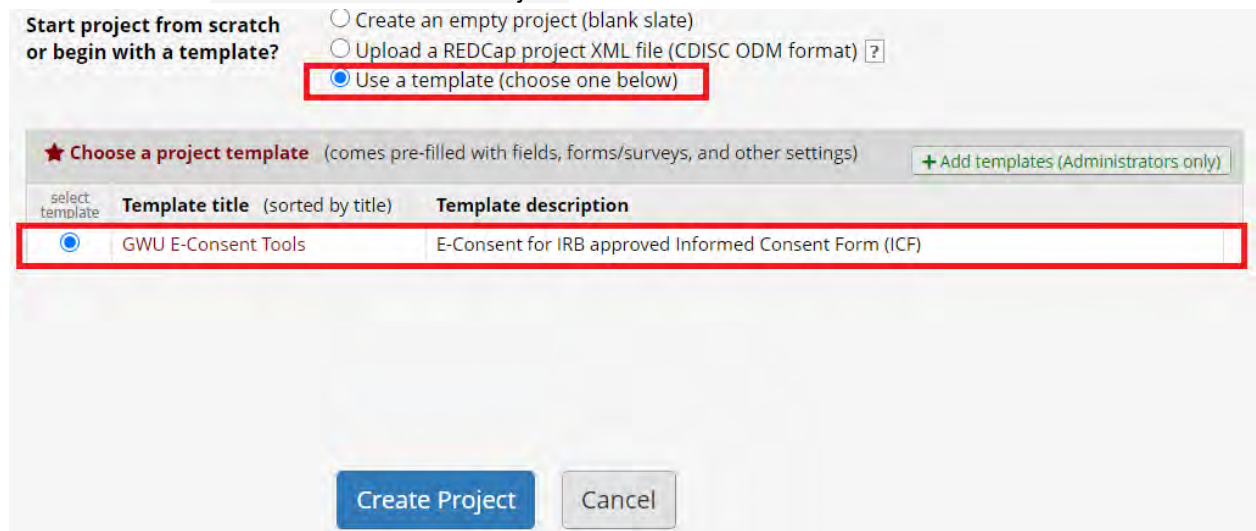
NOTE: an existing IRB-approved consent form PDF is required to utilize this REDCap eConsent Template.

REDCap

1. Sign on to REDCap and click “New Project”



2. Select the “Use a template (choose one below)” option, choose the template called **GWU E-Consent Tools** and then click “Create Project”

A screenshot of the REDCap 'Create Project' form. The form has three radio button options: 'Create an empty project (blank slate)', 'Upload a REDCap project XML file (CDISC ODM format)', and 'Use a template (choose one below)'. The 'Use a template' option is selected and highlighted with a red box. Below these options is a section titled 'Choose a project template' with a subtext '(comes pre-filled with fields, forms/surveys, and other settings)'. There is a '+ Add templates (Administrators only)' button. Below this is a table with two columns: 'Template title (sorted by title)' and 'Template description'. The first row in the table is highlighted with a red box and contains the text 'GWU E-Consent Tools' and 'E-Consent for IRB approved Informed Consent Form (ICF)'. At the bottom of the form are two buttons: 'Create Project' and 'Cancel'.

- Navigate to the Online Designer by clicking 'Project Setup', and then 'Online Designer'

The screenshot shows the REDCap interface for 'George Washington University IRB Consent Tools' (PID 34). The user is logged in as btgerald@gwu.edu. The 'Project Setup' menu item is highlighted with a red box and a red arrow. Below it, the 'Online Designer' button is also highlighted with a red box and a red arrow.

- Identify your consenting requirements from the 'Instrument name' list (you can also follow these steps in the template instrument titled 'Researcher Instructions')

The screenshot shows the 'Data Collection Instruments' page. The 'Researcher Instructions' instrument is circled in red. Four red arrows point to the first four instruments in the list: 'GWU Biomedical Adult Consent', 'GWU Biomedical One Parent Consent', 'GWU Social Behavior One Parent Consent', and 'GWU Social Behavior Adult Consent'.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
GWU Biomedical Adult Consent	33			Choose action	Survey settings + Automated Invitations
GWU Biomedical One Parent Consent	38			Choose action	Survey settings + Automated Invitations
GWU Social Behavior One Parent Consent	25			Choose action	Survey settings + Automated Invitations
GWU Social Behavior Adult Consent	21			Choose action	Survey settings + Automated Invitations
Audio/Video Permission	8			Choose action	Survey settings + Automated Invitations
Researcher Instructions	0		Enable	Choose action	

5. **Delete the instruments/surveys that do not correspond with your consenting requirements** (e.g., if only doing consent for Biomedical Adult, then delete all other forms except research instructions. If only doing Social Behavior Parent consent, then delete other forms such as biomedical adult, biomedical parent, and social behavior adult. You should retain the 'Researcher Instructions' in your project for future reference. To delete an instrument, click 'choose action', then 'delete' as shown below.)

Data Collection Instruments

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

Survey options:
 Survey Queue Survey Login
 Survey Notifications

Automated Survey Invitation options:
 Upload or download Auto Invitations
 Re-evaluate Auto Invitations

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
GWU Biomedical Adult Consent	33			Choose action	Survey settings + Automated Invitations
GWU Biomedical One Parent Consent	38			Rename	Settings + Automated Invitations
GWU Social Behavior One Parent Consent	25			Copy	Settings + Automated Invitations
GWU Social Behavior Adult Consent	21			Delete	Settings + Automated Invitations
Audio/Video Permission	8			Download Instrument ZIP	Settings + Automated Invitations
Researcher Instructions	0		Enable	Choose action	

6. Are you doing tissue banking and/or storing PHI in a database for future research? **If not**, delete the fields that reference tissue banking and storing PHI for future research. **If yes**, retain the tissue banking and/or PHI storage fields so that the REDCap form matches the exact phrasing in your IRB approved consent form. Delete fields with phrasing not included in your IRB approved consent form by clicking the red X button.

Add Field Add Matrix of Fields

Banking of Tissue Specimens: Please indicate your approval of any or all of the following by checking a box next to each statement.

Add Field Add Matrix of Fields

Variable: tissue_v1_2

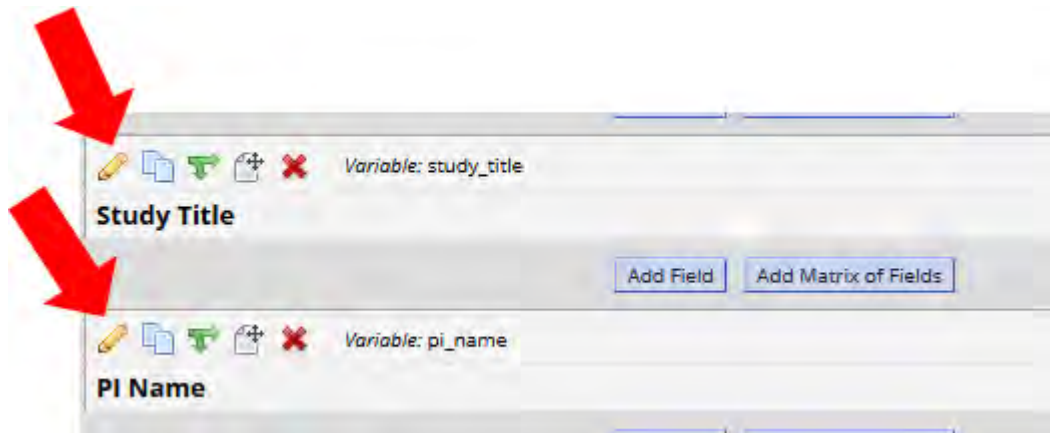
My tissue may be stored in the named bank for future analysis related to this study Yes No

* must provide value Select one option reset

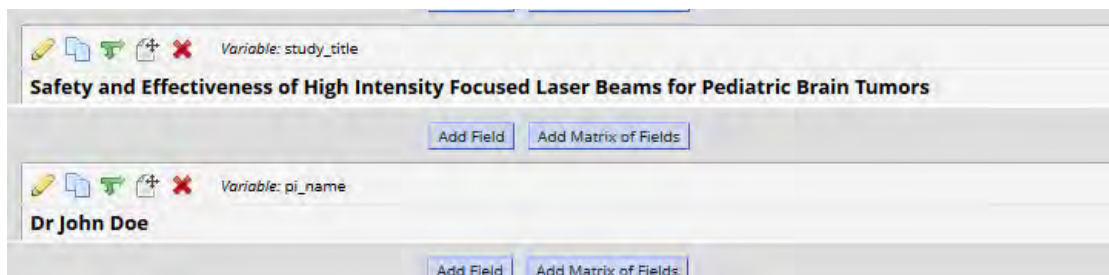
Add Field Add Matrix of Fields

7. Click on your chosen Instrument/survey and edit (by clicking on the pencil icons) the first fields of the consenting survey called Study Title and PI Name so that they list the study name and the name of the PI of your study.

The information should go from this:



To this (include your actual study title and PI name):



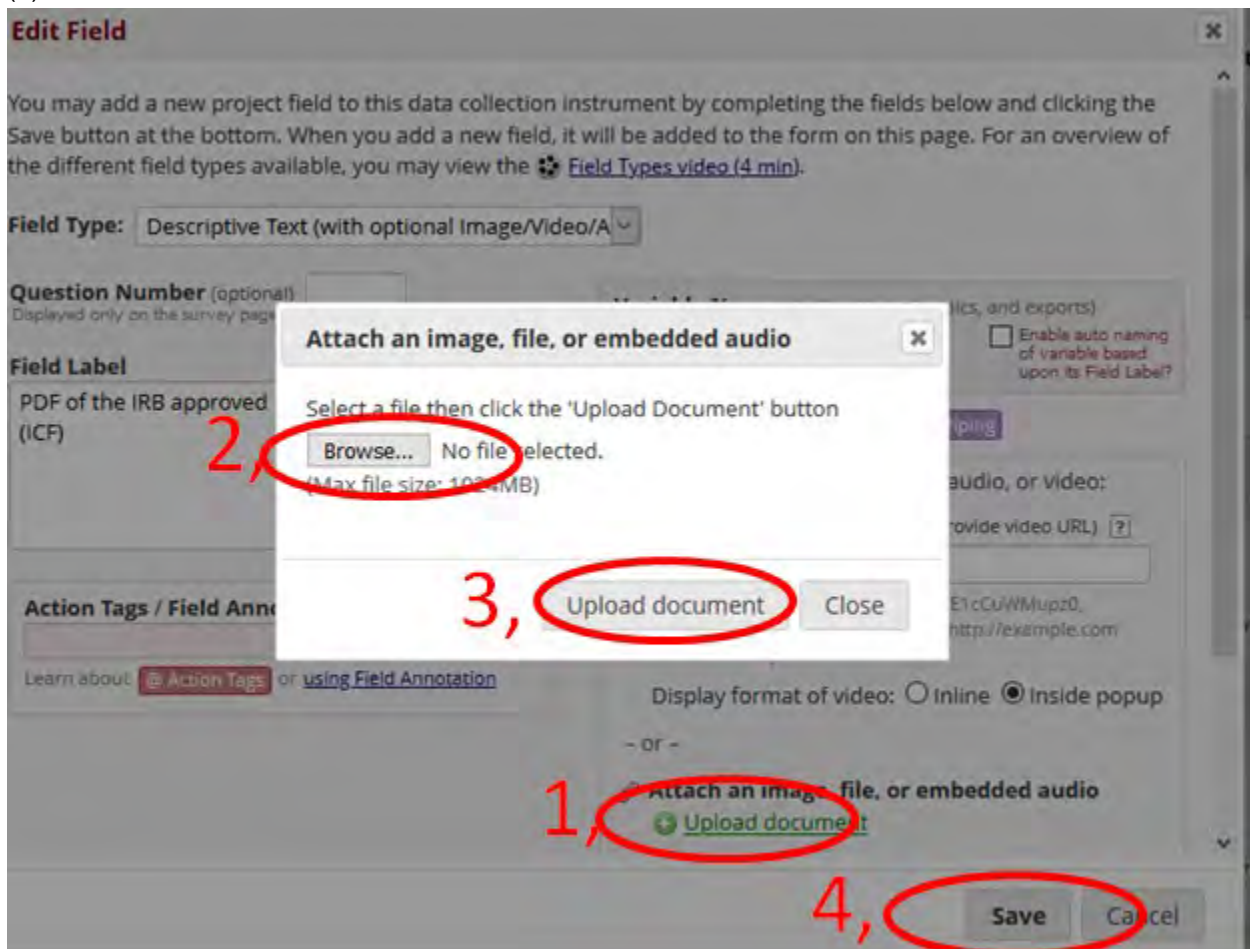
8. Edit the survey field labeled "PDF of the IRB approved Informed Consent Form (ICF)" to attach your approved Informed Consent Form (ICF). Click the pencil as shown below:

NOTE: There will be a PDF form already attached, you can download that form, edit it, and re-upload with the instructions below!

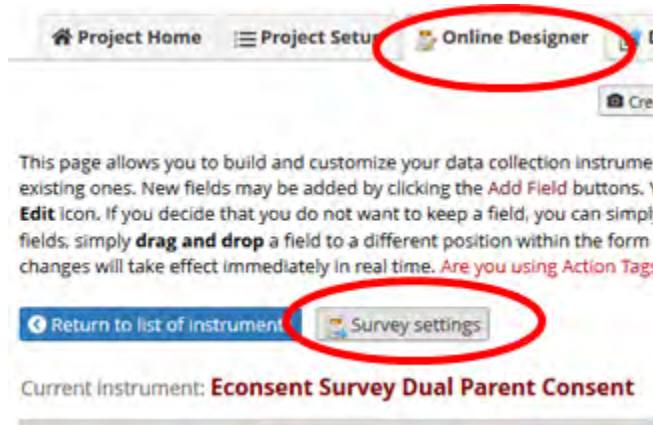


To attach the pdf, in the field window, select:

- (1), "Upload document" .
- (2) Click "Browse" and then find your saved ICF,
- (3) 'upload document', then
- (4) 'Save'.



9. Add consent form PDF download and PDF auto-archiving. Navigate to Survey Settings.



- a. Scroll down to "Allow Participants to download a PDF of their completed responses at end of survey" and selected "Yes"



- b. Still under Survey Settings, scroll down to “PDF Auto-Archiver” and select “Auto-Archiver + e-consent Framework”

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 of 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: -- select a field --

Last name field: -- select a field --

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: -- select a field --

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: -- select a field --

+ Select another signature field

NOTE: 1.) Select “Allow e-consent responses to be edited by users” This will help researchers who want to sign their signatures after users have completed their part.

2.) To capture the signature for the e-consent framework, you must choose the signature line under the “First name field”

We will only choose ONE field, because the signature is entered on ONE line so it should look like this below

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: "Electronic sig"

Last name field:

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:

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:

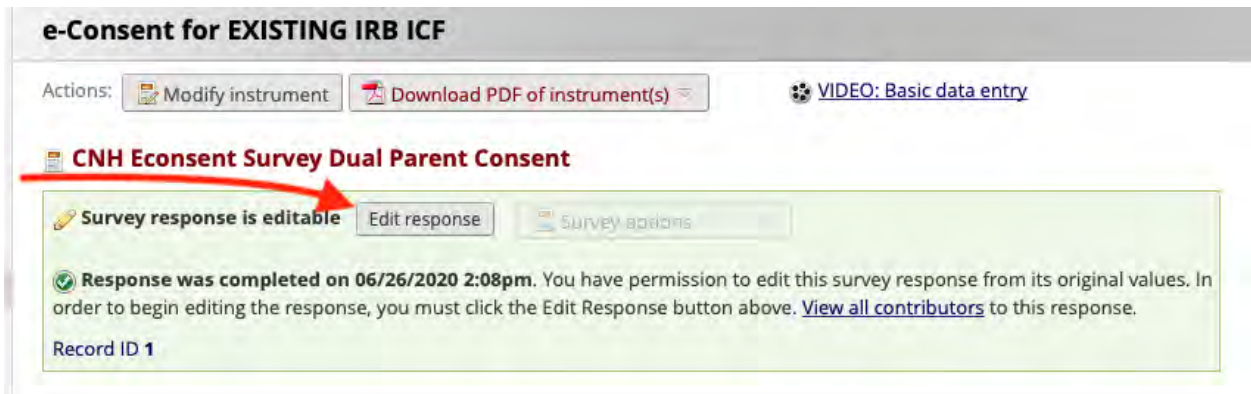
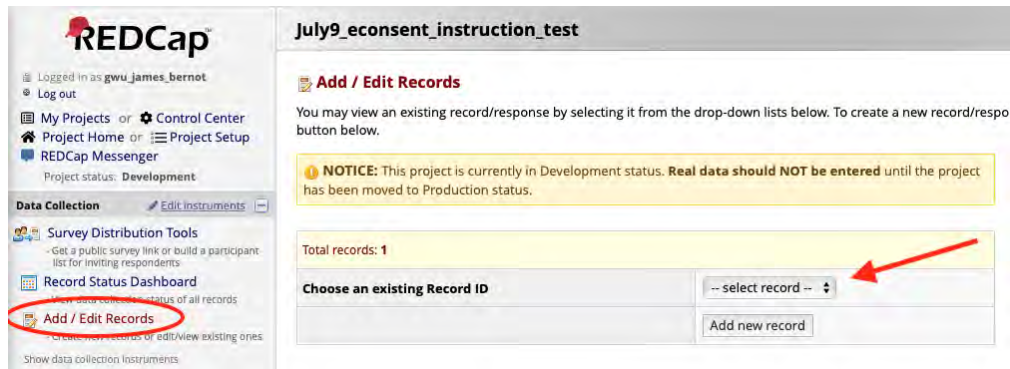
Because this is for “GWU Biomedical Adult Consent” I chose the “signature_adult” field. That is the variable/question where the user inputs their signature. The other variables for the other forms are as followed below!

- GWU Biomedical Adult Consent = signature_adult
- GWU Biomedical Parent Consent= parent_signature
- GWU Social Behavior Parent Consent = parent_signaturesb
- GWU Social Behavior Adult Consent = signature_adultsb

10. Test your project thoroughly. At a minimum, you will need 3 completed test records in your project in order to move your project to Production Mode. You should test (a) the survey element (used by study participants) and (b) Form Mode (used by researchers to add additional information beyond the participant signature).

- a. To test the survey element of the eConsent form (i.e., what the study participant will see), select Survey Distribution Tools on the left-hand navigation menu. Then click Open Public Survey URL to test your eConsent Survey.

- b. You should also test your project in Form Mode (as opposed to Survey Mode) because additional fields are visible in form mode that are not visible to the study participant in survey mode (e.g., PI signature, signature of person obtaining consent, translator ID number, etc.). The survey form is what the participant completes, the Form mode is where you add important information to each record. To add information to test record in Form Mode, select Add/Edit Records on the left-hand Menu (screenshot below). Then select a test record that you created in survey mode following the steps above and click the grey button to “Edit response” (screenshot below).




You can now view the fields that are hidden in survey mode and add additional information to each record (e.g., PI signature, signature of person obtaining consent, translator ID number, etc.).

11. Steps for moving to Production mode are listed below. All projects should be in Production Mode before collecting study subject data (i.e., before consenting any new patients using REDCap for eConsent). Click 'Project Setup' at the top left of the page,



Scroll to the bottom of the page and click move project to production mode.

If you only have test records at this point, select the option to delete all data. If you have consented some study subjects with eConsent in REDCap prior to moving to production mode (this would be unusual and is not recommended), be sure to select the option to “Keep ALL data saved so far” when moving to Production Mode.



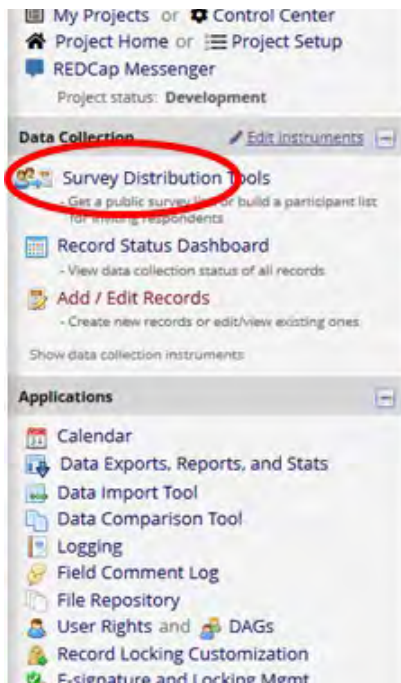
Not started

Move your project to production status

Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can still edit the project in Draft Mode, which will be auto-approved or else might need to be approved by an administrator before taking effect.

Go to [Move project to production](#)

12. Now that your project is in Production Mode, you are ready to begin consenting study subjects electronically. There are two methods in which you can distribute your eConsent survey under Survey Distribution Tools: **(1) The Participant List**, in which you populate this list with the email address of your study subjects and compose your email invitations in REDCap (this also enables you to check if/when a respondent has answered and to send automated reminders) – additional information is available in the REDCap FAQ; or **(2) The Public Survey URL, in which you** copy and paste the public survey into your own email contact message (see screenshot below).



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 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: <https://cri-datacap.org/surveys/?s=C7EANHRFCD>

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











NOTES: YOU CAN CUSTOMIZE YOUR SURVEY ANY WAY THAT DOES NOT INTERFERE WITH DATA COLLECTION! THIS INCLUDES











- Adding a logo
- Adding survey information
- Adding different survey text/color

Check screenshots below for better understanding. These features are located under “survey settings”

— OR —


- Survey Completion Text**
(Displayed after survey is completed as 'thank you' text or as acknowledgement text)

Paragraph **B** *I*          

Thank you for taking the survey.

Have a nice day!











 [How to use Piping here](#)











Survey Title

GWU Biomedical Adult Consent

Title to be displayed to participants at the top of the survey page


- Survey Instructions**
(Displayed at top of survey after title)

Paragraph **B** *I*          


         

Please complete the survey below.

Thank you!

 [How to use Piping here](#)


Survey Design Options:

 [Copy design to other surveys](#)


- Logo**
(Optional: display an image above the survey title)

Add new logo:
 No file chosen
(Images wider than 600 pixels will be downsized to fit page.)
 If using a logo, hide survey title on survey page?

- Use enhanced radio buttons and checkboxes?**
(Includes Yes/No and True/False fields)

Standard radios and checkboxes  [Show example](#)

- Size of survey text**

Large 

- Font of survey text**

Open Sans 

- Survey theme**

Default 