

Remote Consent

Conducting Remote Consent Using REDCap

Presentation Overview

- **Section I:** What is Remote Consent and is it right for my project?
- **Section II:** Building a Remote Consent in REDCap; the Nuts and Bolts
- **Section III:** Mock Consent Demonstration
- **Section IV:** Discussion

REMEMBER.....

We want to show you how REDCap can be a useful tool in your research toolbox.

Be mindful as we present, that each institution and departments within each institution may have differing practices and requirements.

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What is Remote Electronic Consent (e-Consent)?

Another way of conducting the informed consent process....

- The study team and participant are in separate locations.
- Uses an electronic platform (REDCap, DocuSign, or other online application – this presentation focuses on use of REDCap)
- Shows the consent document(s) to the potential study volunteer.
- Signatures are obtained electronically (e-signature).

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Remote e-Consent Potential Benefits

- Improves space utilization in your clinic
- Saves travel time and costs for prospective volunteers.
- Fewer in-clinic screen fails or volunteers who decline participation in clinic.
- The possibility to keep research staff safe when the study is enrolling people who have or may have a communicable disease.

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Remote e-Consent – Potential Challenges

- Volunteers agree to the study but do not arrive for scheduled clinic screen appointment.
- Technology may fail during your consent process.
- May not be feasible for your demographic - (health disparities in research).
- Some people may feel it is less personal than consenting in person

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Determining when to use Remote e-Consent

- Regulatory Considerations
- Sponsor Considerations
- Volunteer Population
- Study Considerations

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Regulatory Considerations

- Does your sponsor allow remote consent?
 - Recommend getting written documentation that your sponsor allows remote consent.
- What are your institutional guidelines?
 - Does your HRPP or IRB have procedures and processes to follow. Review your IRB guidelines or templates to follow?
- Who is your sponsor? (Sponsor-Investigator, Industry Sponsor)

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Study Considerations

What are the specifics of your study?

- Is fasting a required study procedure?
- Is there a washout period for study medications?
- Are consent and study procedures supposed to occur on the same day?
- Is there enough time before your study starts to allow for remote consenting?

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Study Population Considerations

- Who is your study population?
Computer literate?
- Does your population have access to technology/internet?
- What is your potential volunteer's preference?

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Section II:

Nuts and Bolts of Building a Remote Consent in REDCap Conducting a Remote Consent

Project Templates

- The easiest way to create compliant remote consent documents in REDCap, is to use an IRB approved project template (if your institution has one)

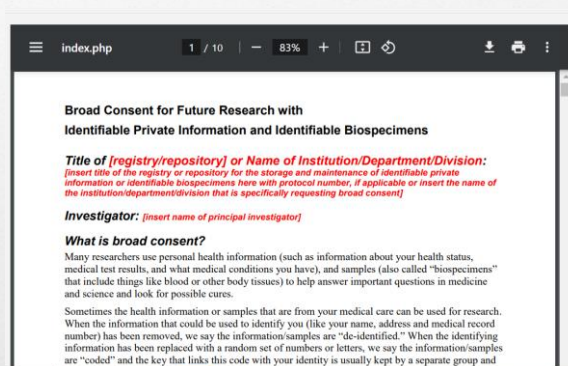
The screenshot shows the 'Project creation options' dialog in REDCap. At the top, there are three radio buttons: 'Empty project (blank slate)', 'Upload a REDCap project XML file (EDXSC ODM format)', and 'Use a template (choose one below)'. The third option is selected. Below this is a section titled 'Choose a project template' with a list of templates. The templates are: 'Basic Demography', 'Classic Database', 'e-Consent', 'Field Embedding Example Project', 'Human Cancer Tissue Biobank', and 'Longitudinal Database (1 arm)'. Each template has a brief description. At the bottom of the dialog are 'Create Project' and 'Cancel' buttons.

Template title (sorted by title)	Template description
<input type="radio"/> Basic Demography	Contains a single data collection instrument to capture basic demographic information.
<input type="radio"/> Classic Database	Contains six data entry forms, including forms for demographic and baseline data, three monthly data forms, and concludes with a completion data form.
<input type="radio"/> e-Consent	Contains instructions and pre-installed settings to help users use e-Consent framework in a process consistent with FDA IRB policies.
<input type="radio"/> Field Embedding Example Project	Contains a single data collection instrument to demonstrate the Field Embedding feature.
<input type="radio"/> Human Cancer Tissue Biobank	Contains five data entry forms for collecting and tracking information for cancer tissue.
<input type="radio"/> Longitudinal Database (1 arm)	Contains nine data entry forms (beginning with a demography form) for collecting data longitudinally over eight different events.

Maintain Integrity of IRB Approved Document

- Attach blank copy IRB approved .pdf for download
- Use inline .pdf or images (.png or .jpg) of each page
 - Includes IRB stamp
 - Preserves formatting and font for as close to paper as possible
 - Prevents errors in transposition

Using an Inline Image of ICF Pages

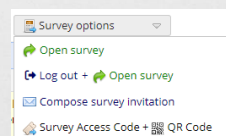


Creating Inline Images of ICF Pages

The screenshot shows the 'Edit Field' dialog in REDCap. The 'Field Type' is set to 'Descriptive Text (with optional Image/Video/Audio/File Attachment)'. The 'Variable Name' is 'icf_pg1_v2'. The 'Field Label' is empty. The 'Action Tags / Field Annotation' section is empty. The 'Embed an external video' option is selected, and the 'Display format of video' is set to 'inline'. The 'Attach an image, file, or embedded audio' option is also visible.

Distributing the Survey

- Email the link
 - Automated Survey Invitation or Alert directly from REDCap (need to collect email address in REDCap before consent)
 - Copy and paste anonymous link or link from within record into email platform outside REDCap
- Real time distribution in video call chat
 - Anonymous Link
 - Make record and send link from form



Provide Participant Copy to Review Before Agreeing to Consent

- Email ahead of time with .pdf attached
- Include a field with .pdf to download that is placed BEFORE field indicating consent decision.

This is a copy of the blank informed consent form for download. Please click on the PDF document below to download and save to your computer.

Attachment: <http://502a-consent-template-sber-2021223.docx> (72.4 KB)

I consent to participate in this study. ☐ Yes ☐ No
* must provide value

reset

<< Previous Page Save & Return Later Next Page >>

Creating Field to Download Blank ICF Copy

Edit 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](#) page.

Field Type: Descriptive Text (with optional image/video/audio/file attachment)

Question Number (optional):

Field Label:

Use the Rich Text Editor: ☐

Variable Name (optional): Field with naming of variable based upon its field label

How to use: [Get Help](#) [Get Help](#) [Get Help](#)

Optional file attachment, image, audio, or video:

☒ Embed an external video (provide video URL)

e.g. <https://www.youtube.com/watch?v=7CtUWkUu0d0>, <https://www.youtube.com/watch?v=7CtUWkUu0d0>

Display format of video: ☐ inline ☐ inside popup

☒ Attach an image, file, or embedded audio

[Remove](#)

Display format of attachment on page:

☒ Link ☐ Inline image/PDF ☐ Audio file (play in embedded player on page) ☐ Downloadable audio (for embedded audio)

(Images wider than 400 pixels will be downloaded to the page)

Save Cancel

Collecting Signatures

1.

Signature of Research Team Member [Add signature](#)
* must provide value

2.

Add signature

Signature of Research Team Member
* must provide value

[Start new](#)

[Save signature](#) [Cancel](#)

3.

Signature of Research Team Member
* must provide value



[signature-2024-02-20-1617.png \(0.01 MB\)](#)

[Remove signature](#)

Save & Return Later

[?](#) **Allow 'Save & Return Later' option for respondents?**

(Allow respondents to leave the survey and return later.)

☒ **Allow respondents to return without needing a return code** [?](#)

NOTE: If you are collecting identifying information (e.g., PII, PHI), for privacy reasons it is HIGHLY recommended that you leave the option unchecked so as to enforce a return code.

☐ **Allow respondents to return and modify completed responses** [?](#)

Save & Return Later: Participant View

YES (initial) NO (initial)

Printed Name of Research Team Member Obtaining Consent

Signature of Research Team Member

Date

[Save & Return Later](#)

Your survey responses were saved!

Survey link for return later: [Survey link for return later](#)

Or if you wish, you may continue with this survey again now: [Continue Survey Now](#)

Save & Return Later: Investigator View

Survey response is editable ☒ Survey options ☐

Response is only partial and is not complete. Response was added on 2024-03-12 14:16. Response was initially created on 2024-03-12 14:16. You have permission to edit this survey response from its original value. In order to begin editing the response, you must click the Edit Response button above. [View all contributors to this response.](#)

Revised ID:

This is a sample consent form for you to see what the final product looks like, and to test out how it would function. This example uses the option to download the blank consent copy. Be sure to delete this instrument before moving to production.

I agree to use of audio/video for educational purposes including ☐

YES (initial) NO (initial)

Printed Name of Research Team Member Obtaining Consent

Signature of Research Team Member

Date

Form Status

Complete? ☒ [Complete](#)

Lock this instrument? ☐ [Lock](#)

[Save & Exit Form](#) [Save & Exit](#)

Save & Return Later: Participant View II

Your survey responses were saved!

You have chosen to stop the survey for now and return at a later time to complete it. To return to this survey, you will need the survey link we provided.

Survey link for returning

You may bookmark this page to return to the survey. OR you can have the survey link emailed to you by providing your email address below. If you do not receive the email soon afterward, please check your junk email folder.

Enter email address

*Your email address will not be associated with or received by your survey responses.

Do if you wish, your new session with this survey again now.



—OFFICE USE ONLY—

Printed Name of Research Team Member Obtaining

Consent

*must provide value

Test Name

Signature of Research Team Member

*must provide value

Signature of Research Team Member

Signature of Research Team Member

Signature of Research Team Member

Signature of Research Team Member

Signature of Research Team Member

Signature of Research Team Member

Date

*must provide value

03-12-2024

Today

or

<< Previous Page

Next Page >>

Save & Return Later

Multi-Signature Consent External Module

- At Boston University, our REDCap e-Consent policy restricts study teams from editing an e-Consent that has been signed and submitted by the participant.
 - Our institutional REDCap e-Consent guidelines instruct study teams to uncheck the 'Allow e-Consent responses to be edited by users?' option in the Survey Settings.
 - To address scenarios where the participant is submitting an asynchronous e-Consent (i.e., remotely and independently), a separate 'Study Personnel' e-Consent is needed.
 - This results in two signed e-Consent PDFs, one signed and submitted by the participant and the other signed and submitted by the study personnel.
 - The Multi-signature Consent External module merges these two documents into one.

Current instrument: **Study Personnel Consent Form v1.0**

Remember to open as a survey
'Leave without saving changes' after survey completion.

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.

e-Consent Framework Options:
For e-Consent it is sometimes required to include the consenting participant's on the final consent form as extra documentation of their identity. Before you click 'Yes', you may also enter the current e-Consent version and e-Consent type for this. You may also enter the current e-Consent version and e-Consent type for this. You may also enter the current e-Consent version and e-Consent type for this.

Participant Name:
First name (last name)

Date of signature:
[date]

Signature of Study Personnel
I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

First Name
[text input]

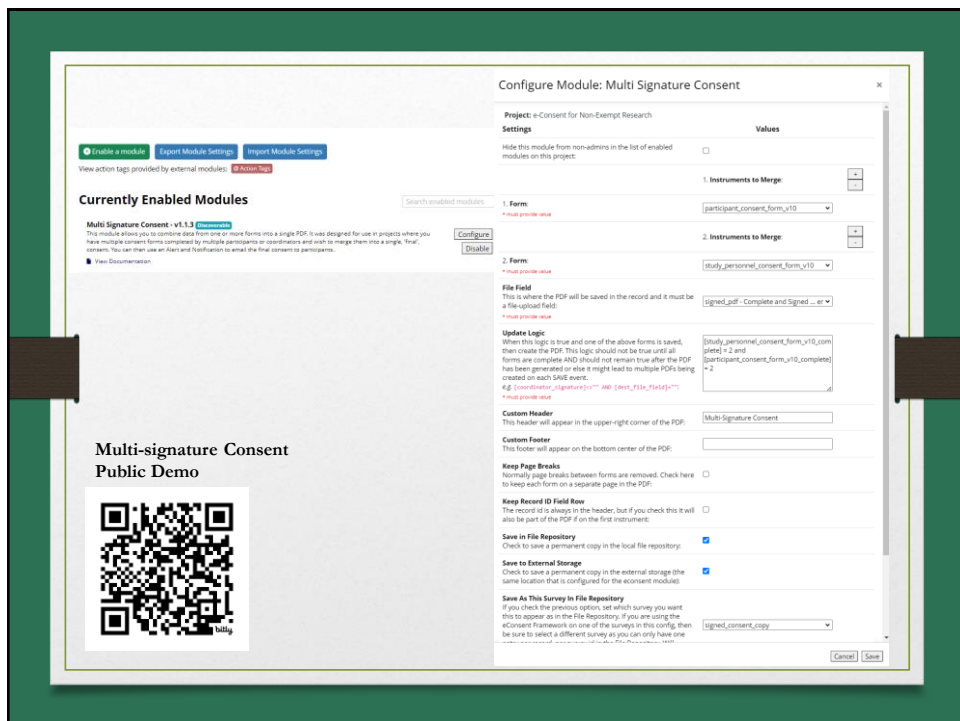
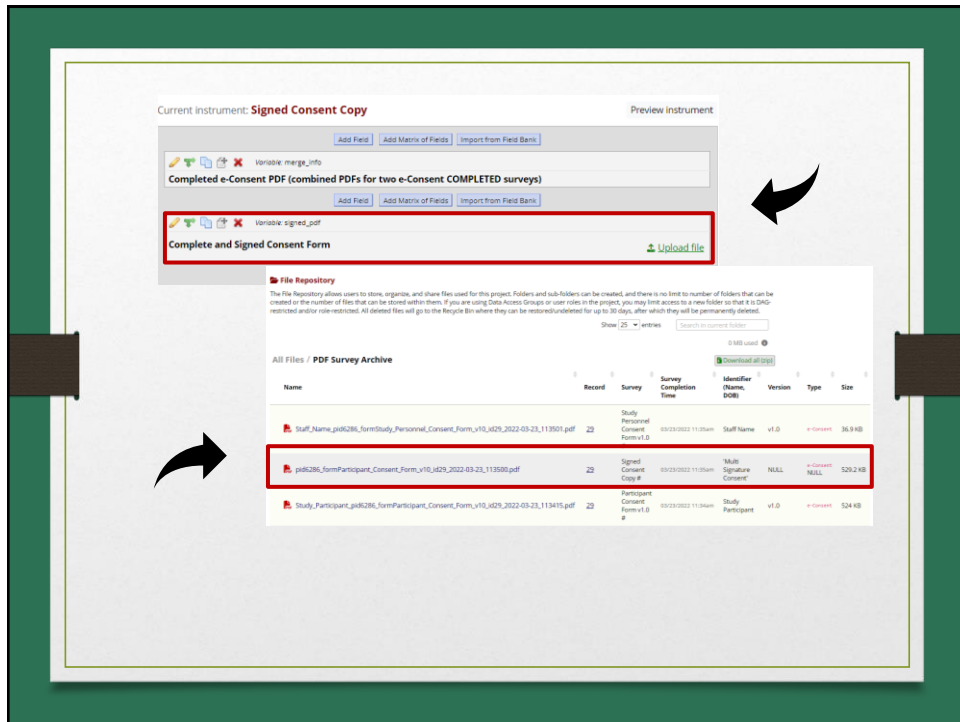
Last Name
[text input]

Signature (if possible sign with finger, stylus or mouse)
[signature input]

Multi Signature Consent External Module

To combine these two separated e-Consent PDFs, we utilize the Multi Signature Consent External Module.

- The Multi Signature Consent EM was developed by Andy Martin (Stanford University).
- It allows you to create a single PDF containing data from multiple REDCap surveys.
- It was designed to merge participant and researcher consent signatures into a single final PDF document.



REDCap e-Consent Framework Survey Setting

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 this 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 this PDF hard-copy will be archived in the File Repository. [Read more](#)

☒ Allow e-Consent responses to be edited by users?

e-Consent version:

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 value blank/unselected.)

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

e-Consent type:

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 date field and field, a signature field, or a combined 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 when 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 fields 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 another signature field](#)

E-Consent Framework Certification Page

Page 11 of 11

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

e-Consent Template
Please complete the survey below.
Thank you!

This is a sample consent form for you to see what the final product looks like, and to test out how it would function. This example uses the option to download the blank consent copy. Be sure to delete this instrument before moving to production.

Permissions to Take Part in a Research Study

FOR THE NATIONAL WHITE PAPER PROJECT
We have Reviewed and Approved Your Consent

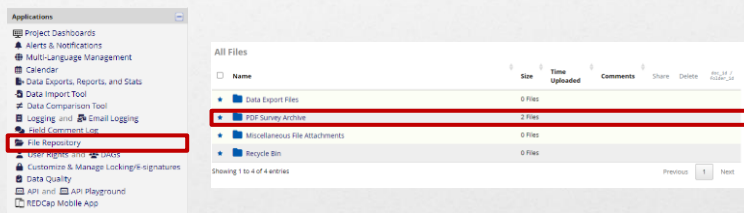
If you are having trouble viewing the PDF or if your browser does not support viewing multi-page PDFs, you may open the PDF in a new tab window. [View PDF](#)

☒ I certify that all of my 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](#)

E-Consent Framework Auto-Archiver and File Repository



Providing a Copy of Signed ICF

[Close survey](#)

Thank you for taking the survey.

Have a nice day!

Enter your email to receive confirmation message?
A confirmation email is supposed to be sent to all respondents that have completed the survey, but because your email address is not on file, the confirmation email cannot be sent automatically. If you wish to receive it, enter your email address below.

[Send confirmation email](#)

* Your email address will not be associated with or stored with your survey responses.

Download your survey response (PDF): [Download](#)

Providing a Copy of Signed ICF

1. Allow participants to download a PDF of their responses at end of survey? Yes ☐ No ☒

2. Send confirmation email? (Email the respondent when they complete the survey) Yes ☒ No ☐

3. Include PDF of completed survey as attachment

Warning: Since email is not considered a secure form of communication, the PDF attachment option is NOT recommended if the survey contains questions asking for identifying information (e.g., PIN).

Note: Because the e-Consent Framework option is enabled on this page, the PDF included here will not be the full-length PDF. It will be the compact PDF, which omits unanswered questions and unselected choices.

From: [display name (optional)] To: [email address]

Subject: [text]

Send test email

Paragraph
B I U
Paragraph
Fullstop

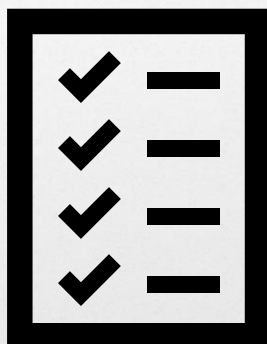
Attachment: Choose file Use file chosen

Section III:

Mock Consent Demonstration



Remote Consent Readiness



Remote Consent Readiness



Sponsor approval for remote consent

Remote Consent Readiness

- ✓ Sponsor Approved for remote consent
- ✓ IRB Approved for remote consent

Remote Consent Readiness

- ✓ Sponsor Approved for remote consent
- ✓ IRB Approved for remote consent
- ✓ REDCap Remote Consent Built and Permissions Granted

Remote Consent Readiness

- ✓ Sponsor Approved for remote consent
- ✓ IRB Approved for remote consent
- ✓ REDCap Remote Consent Built and Permissions Granted
- ✓ Delegated on DOA to perform informed consent

Add A New Record

REDCap Messenger
Contact REDCap administrator

Project Home and Design

- Project Home
- Project Setup
- Designer
- Dictionary
- Codebook
- Project status: Production

Data Collection

- Survey Distribution Tools
- Record Status Dashboard
- Add / Edit Records
- Show data collection instruments

Applications

- Project Dashboards
- Alerts & Notifications
- Multi-Language Management
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging and Email Logging
- Field Comment Log
- File Repository
- User Rights and DAGs
- Data Quality
- REDCap Mobile App
- SCTR Website

SCTR - Biomedical Informatics Center (BIMC)

RPN Mock Consent Presentation P1D: 62628

Record Status Dashboard (all records)

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

Displaying: [Default dashboard] | Page 1 of 1: "1" through "2" of 2 records



+ Add new record

Displaying: Instrument status only | Lock status only | All status types

Participant ID	Participant Information To Be Completed By Study Staff	Inclusion/Exclusion	Patient Contact	Medical University of South Carolina CONSENT TO BE A RESEARCH SUBJECT	Informed Consent Documentation
1					
2					

Study Team Tools

Participant ID 1

Data Collection Instrument	Status
Participant Information To Be Completed By Study Staff	
Inclusion/Exclusion	
Patient Contact	
Medical University of South Carolina CONSENT TO BE A RESEARCH SUBJECT (survey)	
Informed Consent Documentation	

Note: These tools (instruments) were all added in addition to the MUSC eConsent template for purposes of this demonstration.

Survey Invitation to Participant

CAUTION: External

Hello,

Thank you for your interest in the Mock RPN Study. This email contains the electronic consent documents. A Research Coordinator will verbally review the documents and answer all questions before you sign.

You may open the document in your web browser by clicking the link below:
[MUSC Informed Consent Form \(HIPAA Embedded\)](#)

If the link above does not work, try copying the link below into your web browser:
<https://rc1.redcap.unc.edu/surveys/?s=VmPl6vdl.qdgaxSip>

This link is unique to you and should not be forwarded to others. You will receive a copy of the documents after you sign. Please let the research staff member know if you have any questions. We greatly appreciate your time and consideration in our study.

Thank you so much,
Study Team



Time Saver Tool

Schedule your survey invitation
delivery

Send Survey Invitation to Participant

Info
Survey title: Medical University of South Carolina Final CONSENT TO BE A RESEARCH SUBJECT

When should this email be sent?
☒ Immediately
At specified time:
The time must be for the time zone America/New_York, in which the current time is 03/05/2024 10:55.

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

Compose message
From:
(select any project user to be the "Sender")
To:
Or provide another email:
(NOTE: Any email address manually entered above will be used only this one time when sending an survey invitation. Any other invitations sent out at other times will instead go to the email address found in the Participant List for this participant.)
Subject:

Send test email

Send Invitation Cancel



Helpful Tips

Add Study information to fillable fields for participants


Send Survey Invitation to Participant "1"

Compose message
From:
(select any project user to be the "Sender")
To:
Or provide another email:
(NOTE: Any email address manually entered above will be used only this one time when sending an survey invitation. Any other invitations sent out at other times will instead go to the email address found in the Participant List for this participant.)
Subject:

Send test email




Send Invitation Cancel

Please take this survey.
You may open the survey in your web browser by clicking the link below:
[survey-link]
If the link above does not work, try copying the link below into your web browser:
[survey-url]
This link is unique to you and should not be forwarded to others.




Participants can be skeptical of opening suspicious emails and clicking on links.

Today

- 
RS RPN Stu...
11:26 AM
 Please take this survey. Y...
- 
macnich...
2/27/24
 Thank you for your intere...
- 
macnich...
2/27/24
 mock consent t... Please take this survey. Y...

Electronic PRN Consent Form


RPN Study Team <macnichd@musc.edu>
 To: Macnicholas, Della M
 Today at 11:26 AM

Retention: MUSC - Inbox Expires: 08/25/2024.


Please take this survey.

You may open the survey in your web browser by clicking the link below:
[Medical University of South Carolina CONSENT TO BE A RESEARCH SUBJECT](https://redcap.musc.edu/surveys/?s=5VmXCvFa7SrCh)
<https://redcap.musc.edu/surveys/?s=5VmXCvFa7SrCh>

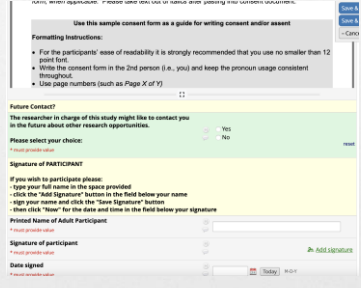
If the link above does not work, try copying the link below into your web browser:
<https://redcap.musc.edu/surveys/?s=5VmXCvFa7SrCh>

This link is unique to you and should not be forwarded to others.


Different Screen Views

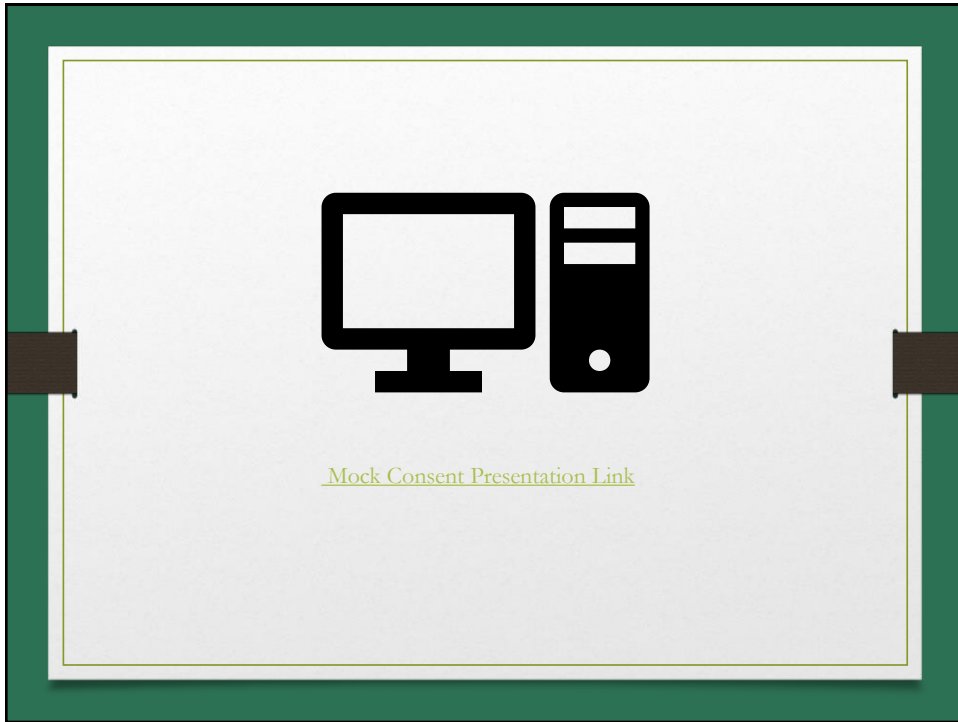


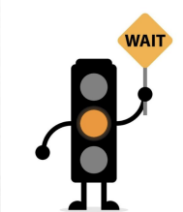
Coordinator View



Participant View







Caution!
Orange Light!
DO NOT
PROCEED!

RPN Mock Consent Presentation

PID #2028

[Record Home Page](#)

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.


[Choose action for record](#)

Participant ID 1

Data Collection Instrument	Status
Participant Information To Be Completed By Study Staff	
Inclusion/Exclusion	
Patient Contact	
Medical University of South Carolina CONSENT TO BE A RESEARCH SUBJECT (survey)	
Informed Consent Documentation	

Legend for status icons:

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



If a participant does not complete all required fields before submission, the coordinator will get an **orange** light. The coordinator can review the consent and real time to provide instructions to complete the form before proceeding.

South Carolina CONSENT TO BE A RESEARCH

Signed Consent – Next Steps

Note: There are multiple ways to share a signed consent. In this example, the coordinator downloads the fully signed consent directly from REDCap to email it to the participant. You must follow your Institutional, Regulatory and Study Team's guidelines for distributing the fully signed ICF.

Optional Instruments – 101

*Permissions are required to edit/add instruments to REDCap Projects

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey related options
Participant Information To Be Completed By Study Staff	3		Enable	Choose action	
Inclusion/Exclusion	5		Enable	Choose action	
Patient Contact	11		Enable	Choose action	
Medical University of South Carolina CONSENT TO BE A RESEARCH SUBJECT	8			Choose action	Survey settings Automated Invitations
Informed Consent Documentation	11		Enable	Choose action	

When building your eConsent in REDCap, you can access the REDCap Instrument Library to look for instruments that you can import and then edit for you specific project needs

Keyword search: [Search the library](#)

Search options:
Language: [All](#)
Type: [show all](#)
Minimum downloads:
Recent additions: [show all](#)
Curated by REDLOC?: [show all](#)

Found 38 results matching your search

Title	Downloads
➤ B&S Inclusion Exclusion Verification Form	45
➤ COHA - Inclusion Exclusion Criteria Form	100
➤ The Upstate Bias Checklist: A Checklist for Assessing Bias in Health Professions Education CONTENT	15
➤ Inclusion Exclusion HFPEF	10
➤ National Pediatric Readiness Project (NPRP) Checklist Pilot	7
➤ CDISC CDASHIG v2.1 Inclusion/Exclusion Criteria ★	85
➤ Inclusion/Exclusion	173
➤ Inclusion/Exclusion	118
➤ ISAR Inclusion Criteria	10
➤ Abbreviated 2q PCL-C ★	135
➤ Abbreviated 6q PCL-C (Scored) ★	44
➤ Abbreviated 6q PCL-C (Scored) ★	31
➤ Abbreviated PCL-C ★	47
➤ Abbreviated PCL-C (Scored) ★	41
➤ Mentoring Match Assessment	3

Found 38 results matching your search

Didn't find what you were looking for? [Suggest a validated instrument for library inclusion](#)

Title	Downloads
► B&S Inclusion Exclusion Verification Form	45
▼ COHA - Inclusion Exclusion Criteria Form	100

Details:

Institution: The Ohio State University

Contact: Ashley Smith

Contact email: smith.8134@osu.edu

Submitted by: Ashley Smith

Description: This form is for use to list all inclusion and exclusion criteria for enrollment into the clinical trial. This form is set up that all inclusion criteria and none of the exclusion criteria must be met in order to confirm eligibility of the patient.

Acknowledgement: Created by The Ohio State University CCTS Research Informatics Services and the Blue Buffalo Veterinary Clinical Trials Office.

Terms of use: Please note that any publication that results from a project utilizing this REDCap instrument should cite grant support (National Center for Advancing Translational Sciences, Grant UL1TR001070).

Last updated: February 21, 2019

[View as web page](#)

[View as PDF](#)

NOTE: PDFs of non-English instruments may not render correctly here, but will render correctly in REDCap projects.

[Import into my REDCap project](#)

► The Upstate Bias Checklist: A Checklist for Assessing Bias in Health Professions Education CONTENT 15

[Return to REDCap](#)

Viewing instrument as web page

The table below displays the data collection instrument as it would appear when viewed in REDCap.

COHA - Inclusion Exclusion Criteria Form

[Editing existing record](#)

Date of Visit [Today](#) D-M-Y

**The use of prednisone is permitted in this clinical trial if dogs have been receiving prednisone for at least 2 weeks prior to study entry and disease progression has been documented while on prednisone. The dose of prednisone should not exceed 1 mg/kg once per day.*

Inclusion Criteria

Dogs diagnosed with histologically or cytologically confirmed spontaneous lymphoma or solid tumors are eligible to be enrolled. The patient may have failed standard therapy, or there may be no other known effective antineoplastic therapeutic options, or the owner may elect to enter the patient in lieu of standard therapy.

* must provide value

☐ Yes ☐ No [reset value](#)

Dogs with lymphoma must have at least 2 peripheral lymph nodes that measure greater than or equal to 2cm in diameter.

Dogs with solid tumors must have a tumor mass that measures greater than or equal to 2cm and is accessible for repeated biopsy.

* must provide value

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The Upstate Bias Checklist: A Checklist for Assessing Bias in Health Professions Education CONTENT

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Title	Downloads
► B&S Inclusion Exclusion Verification Form	45
▼ COHA - Inclusion Exclusion Criteria Form	100

Details:

Institution: The Ohio State University

Contact: Ashley Smith

Contact email: smith.8134@osu.edu

Submitted by: Ashley Smith

Description: This form is for use to list all inclusion and exclusion criteria for enrollment into the clinical trial. This form is set up that all inclusion criteria and none of the exclusion criteria must be met in order to confirm eligibility of the patient.

Acknowledgement: Created by The Ohio State University CCTS Research Informatics Services and the Blue Buffalo Veterinary Clinical Trials Office.

Terms of use: Please note that any publication that results from a project utilizing this REDCap instrument should cite grant support (National Center for Advancing Translational Sciences, Grant UL1TR001070).

Last updated: February 21, 2019

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NOTE: PDFs of non-English instruments may not render correctly here, but will render correctly in REDCap projects.

[Import into my REDCap project](#)

► The Upstate Bias Checklist: A Checklist for Assessing Bias in Health Professions Education CONTENT 15

Current instrument: **Inclusion/Exclusion** Preview instrument

IRB#: XXXX-XXXX
Mock Consent - RPN Presentation

Inclusion:
All fields MUST be answered "Yes" for the subject to meet inclusion criteria

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: inclua_pat_signed_consent
Patient signed and dated informed consent prior to study-specific screening procedures ☐ Yes ☐ No [reset](#)

Variable: inclua_at_least_18_yo
Patient is male or female at least 18 years of age. ☐ Yes ☐ No [reset](#)

Exclusion:
All responses MUST be "No" for subject to meet all exclusion criteria

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: exclusion_priv_refusation
Participant unable or unwilling to participate. ☐ Yes ☐ No [reset](#)

Variable: inclusionexclusion_met
Patient has met all inclusion/exclusion criteria and ☐ Yes ☐ No [reset](#)

Current instrument: **Inclusion/Exclusion** Return to edit view

NOTE: Please be aware that branching logic and calculated fields will not function on this page. They only work on the survey pages and data entry forms.

IRB#: XXXX-XXXX
Mock Consent - RPN Presentation

Inclusion:
All fields MUST be answered "Yes" for the subject to meet inclusion criteria

Patient signed and dated informed consent prior to study-specific screening procedures ☐ Yes ☐ No [reset](#)

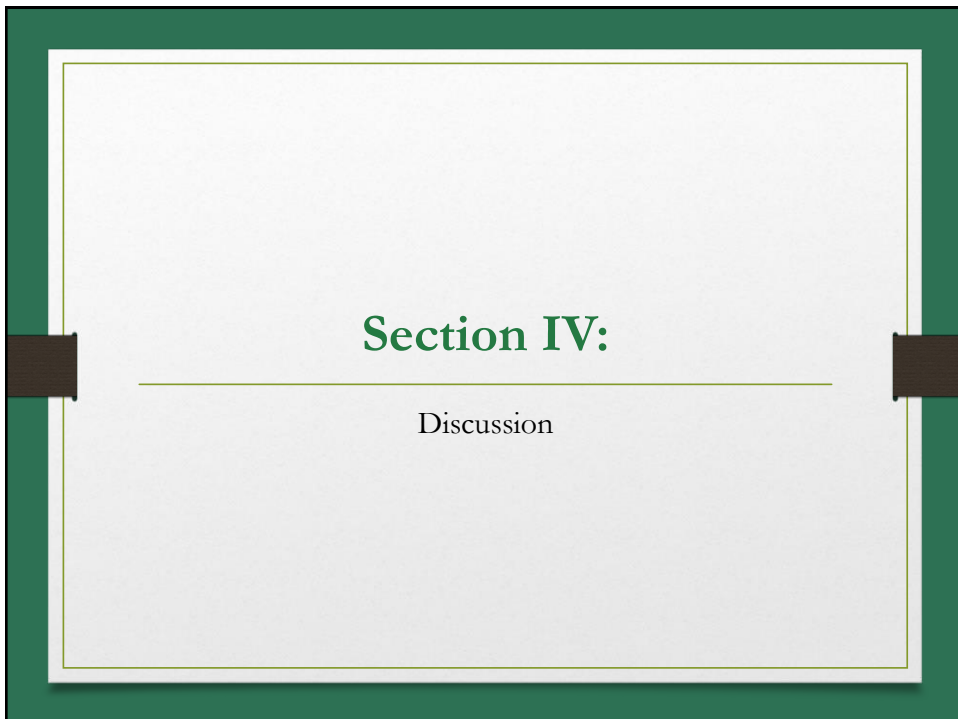
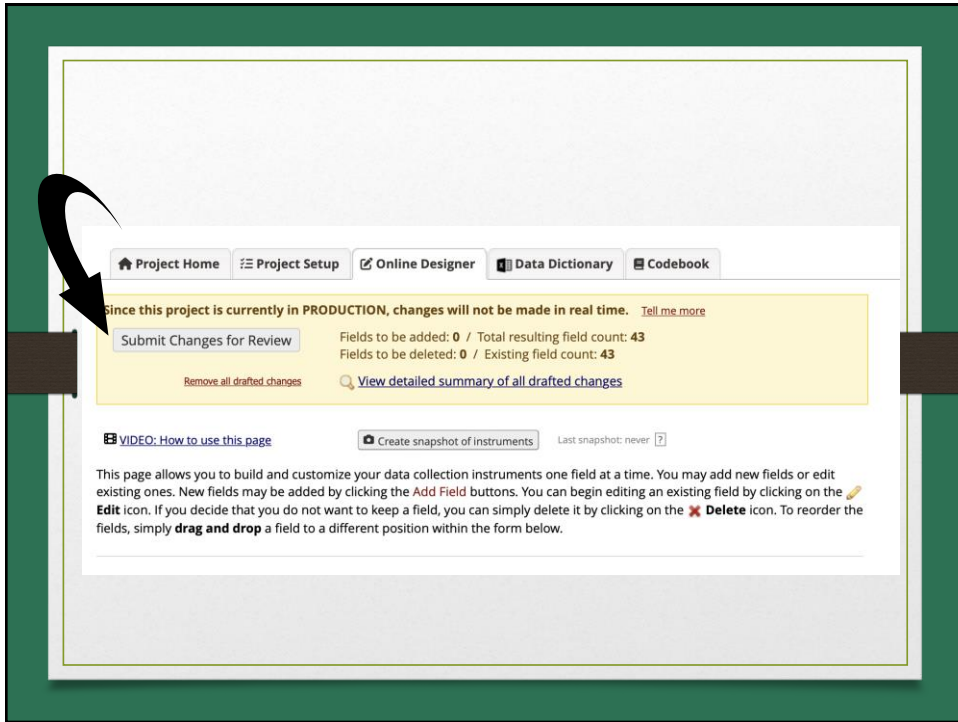
Patient is male or female at least 18 years of age. ☐ Yes ☐ No [reset](#)

Exclusion:
All responses MUST be "No" for subject to meet all exclusion criteria

Participant unable or unwilling to participate. ☐ Yes ☐ No [reset](#)

Patient has met all inclusion/exclusion criteria and qualifies to be treated on-study? ☐ Yes ☐ No [reset](#)

Participant Status
☐ Enrolled ☐ Screen Fail [reset](#)



SCENARIO #1
HOW WOULD YOU RESPOND?

You have an hour scheduled for each remote informed consent visit. Your prospective volunteer requires more than the scheduled time.

What do you do?

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SCENERIO #2
HOW WOULD YOU RESPOND?

You log on to Web-based meeting to conduct a remote consent, and the prospective volunteer is there with their partner. The partner shares that they are interested in participating and ask if they can be present during the consent discussion and sign consent.

What would you do?

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SCENERIO #3 HOW WOULD YOU RESPOND?

You have conducted your informed consent discussion, and the volunteer signs and dates the eConsent.
Then Technology Fails....

What are your options?

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AVOIDING RECRUITMENT BIASES

- How do you make sure you include prospective volunteers do not have access to remote consent to avoid bias?

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Resources

BMC/BU Medical Campus:

- [eConsent Tools and Guidance](https://www.bumc.bu.edu/ctco/resources-library/e-consent-tools-and-guidance/) (this is live link) (<https://www.bumc.bu.edu/ctco/resources-library/e-consent-tools-and-guidance/>)
- [REDCap Help](#)
- [REDCap FAQ](#) (only accessible once logged in)
- [REDCap Training Videos](#) (only accessible once logged in)

MUSC:

- <https://medicine.musc.edu/departments/centers/bmic/projects/redcap>

UF/FSU:

- <https://www.ctsi.ufl.edu/research/study-design-and-analysis/redcap/> (UF)
- <https://ctsa.research.fsu.edu/resources/ncrt-ce/redcap-access/> (FSU)

UVM:

- <https://www.med.uvm.edu/clinicalresearch/informaticscore> (detailed information links only accessible with login)