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.

3

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).

4

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.

5

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

6

Determining when to use Remote e-Consent

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

7

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)

8

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?

9

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?

10

Section II:

Nuts and Bolts of Building a Remote Consent in REDCap

Conducting a Remote Consent

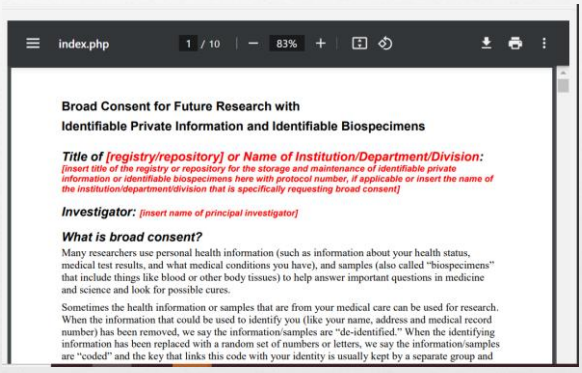
Project Templates

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

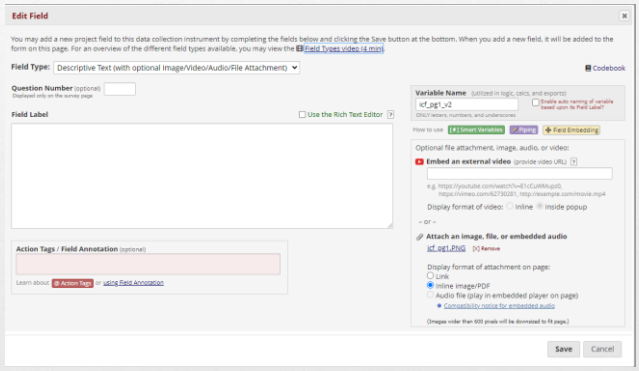
Maintain Integrity of IRB Approved Document

- 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

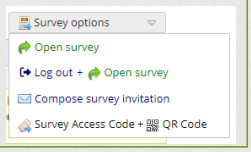


Creating Inline Images of ICF Pages



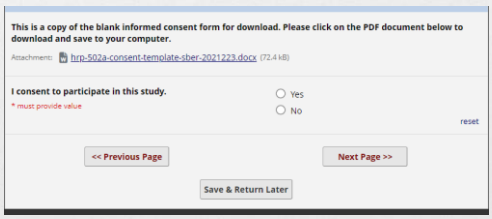
Distributing the Survey

- 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

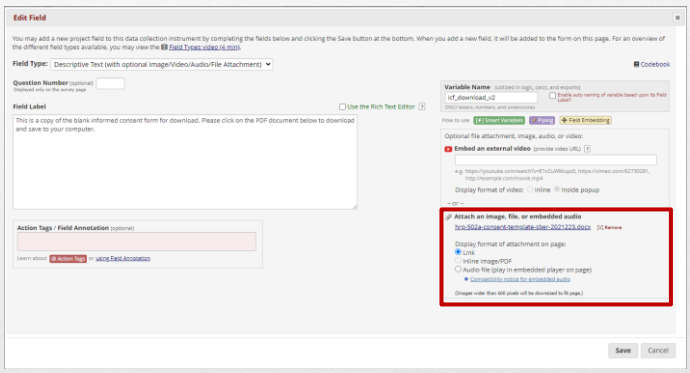


Provide Participant Copy to Review <u>Before</u> Agreeing to Consent

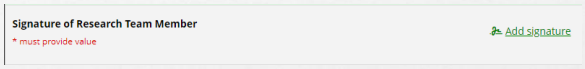
- Email ahead of time with .pdf attached
- Include a field with .pdf to download that is placed BEFORE field indicating consent decision.



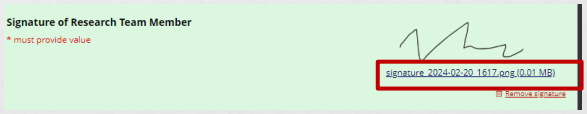
Creating Field to Download Blank ICF Copy



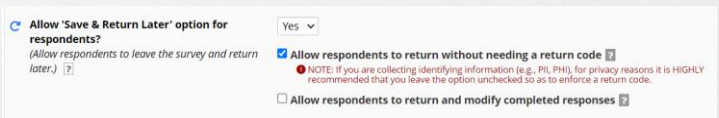
Collecting Signatures

1. 

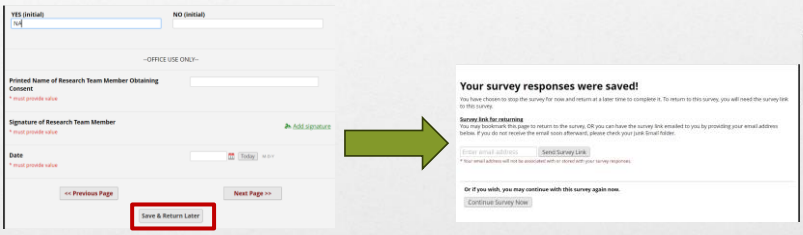
2. 

3. 

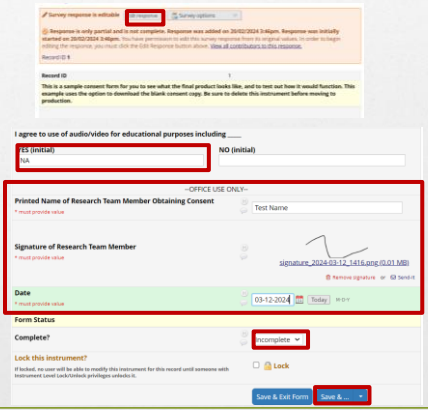
Save & Return Later



Save & Return Later: Participant View



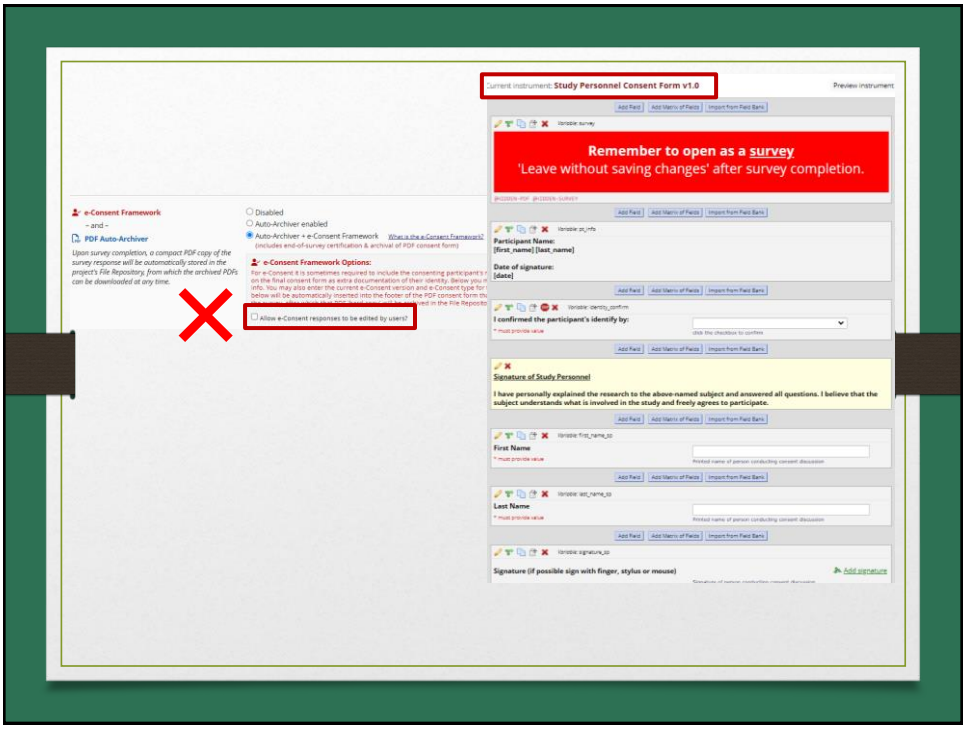
Save & Return Later: Investigator View



Save & Return Later: Participant View II

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.

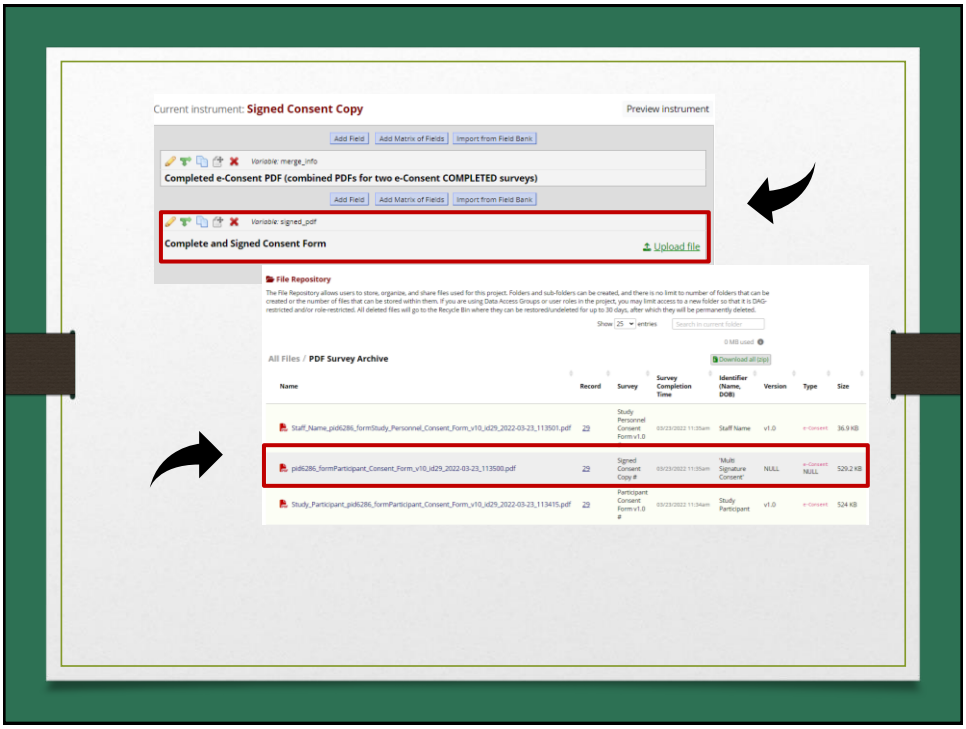


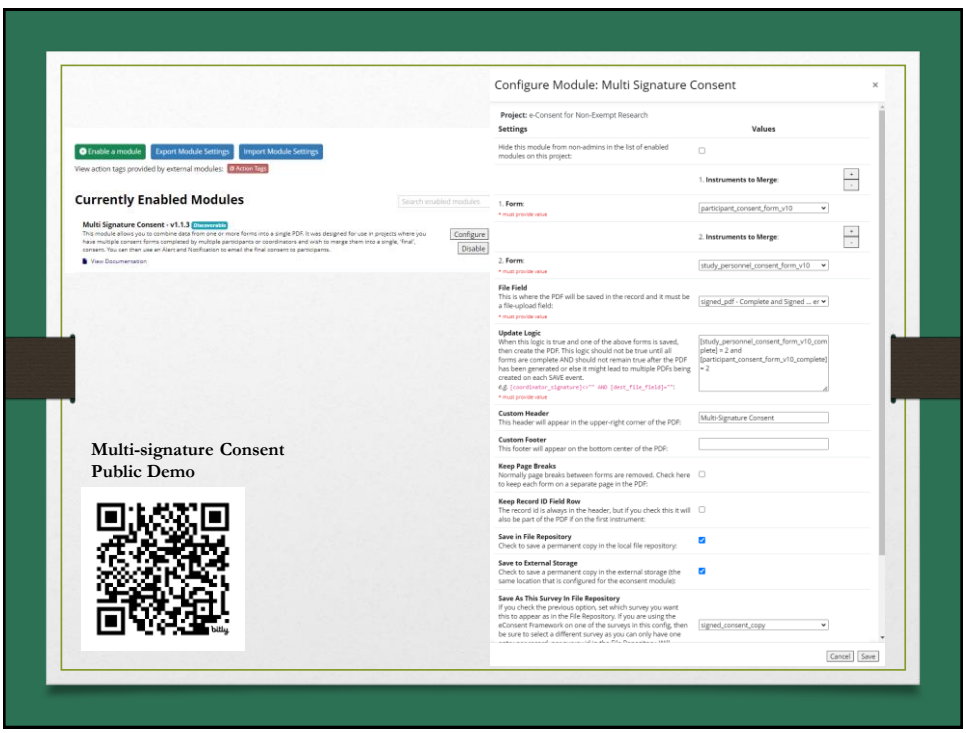
Multi Signature Consent External Module

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

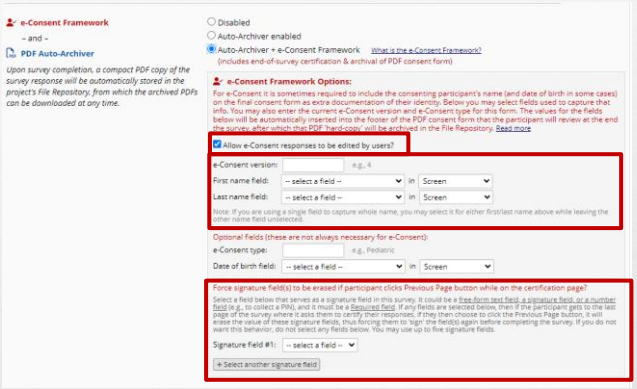
- The Multi Signature Consent EM was developed by Andy Martin (Stanford University).
- It allows you to create a single PDF containing data from multiple REDCap surveys.
- It was designed to merge participant and researcher consent signatures into a single final PDF document.

26

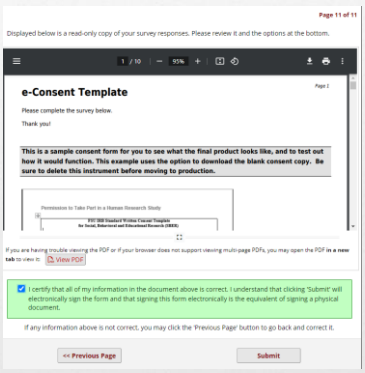

Current instrument: Signed Consent Copy
Preview instrument
Add Field
Add Matrix of Fields
Import from Field Bank
Variable: merge_info
Completed e-Consent PDF (combined PDFs for two e-Consent COMPLETED surveys)
Add Field
Add Matrix of Fields
Import from Field Bank
Variable: signed_pdf
Complete and Signed Consent Form
Upload file
File Repository
All Files / PDF Survey Archive
Name
Record
Survey
Survey Completion Time
Identifier (Name, DOB)
Version
Type
Size


Configure Module: Multi Signature Consent
Project: e-Consent for Non-Exempt Research
Settings
Values
Enable a module
Export Module Settings
Import Module Settings
Currently Enabled Modules
Multi Signature Consent - v1.1.3
Configure
Disable
Multi-signature Consent
Public Demo

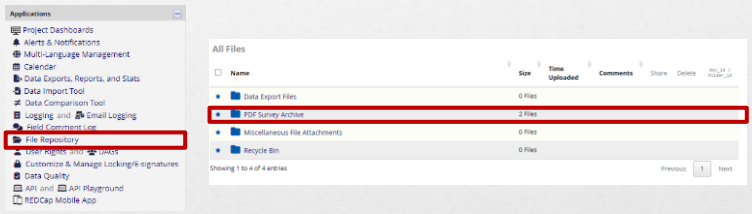
REDCap e-Consent Framework Survey Setting



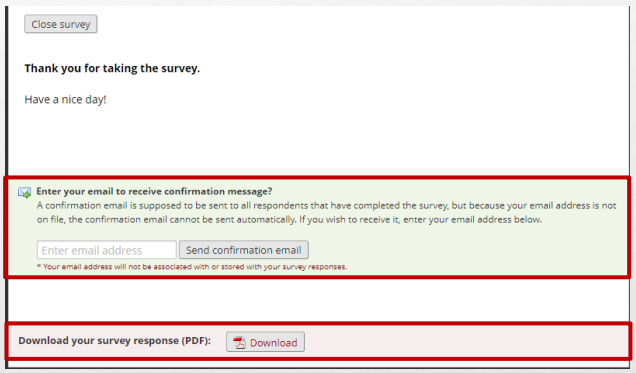
E-Consent Framework Certification Page



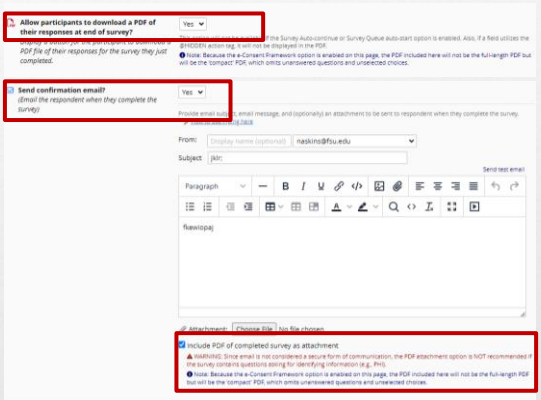
E-Consent Framework Auto-Archiver and File Repository



Providing a Copy of Signed ICF



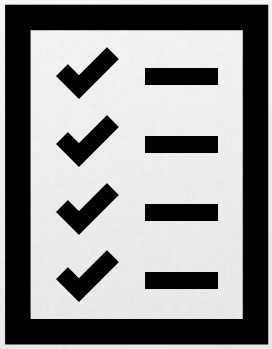
Providing a Copy of Signed ICF



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

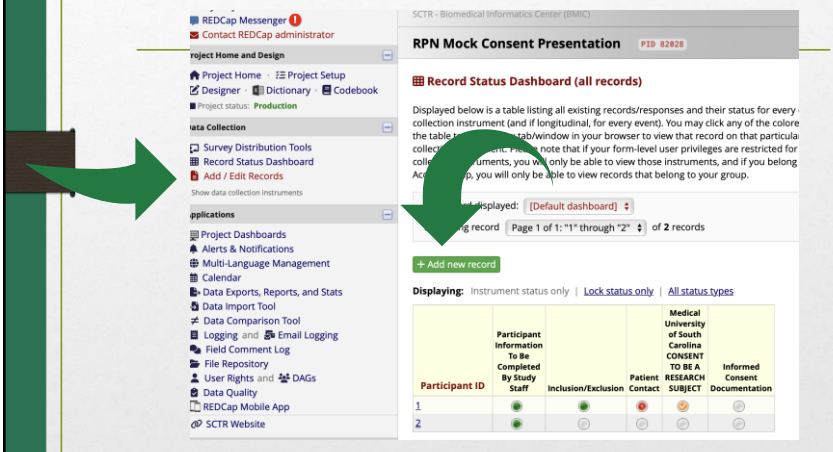
Remote Consent Readiness

- ✓ 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



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=VmPi6vdLqdqaxSjp

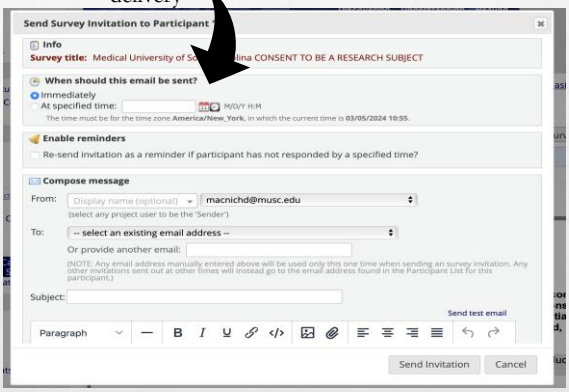
This link is unique to you and should not be forwarded to others. You will receive a copy of the documents after you sign. Please let the research staff member know if you have any questions. We greatly appreciate your time and consideration in our study.

Thank you so much,

Study Team

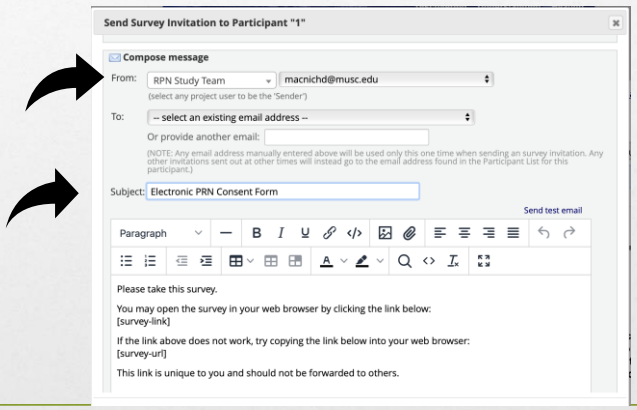
Time Saver Tool

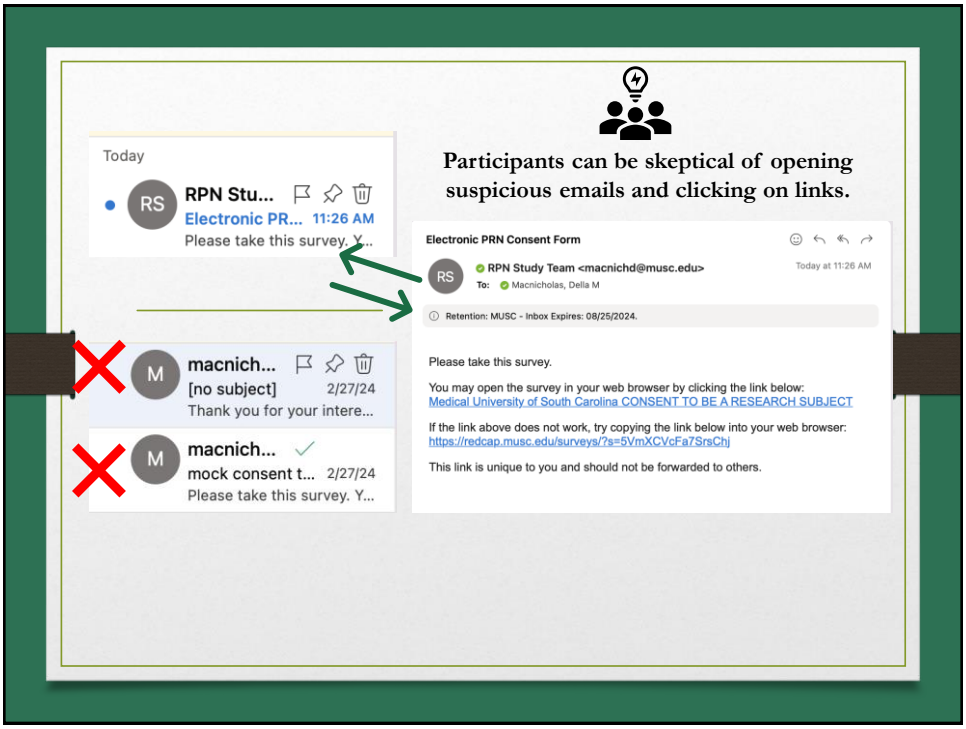
Schedule your survey invitation delivery

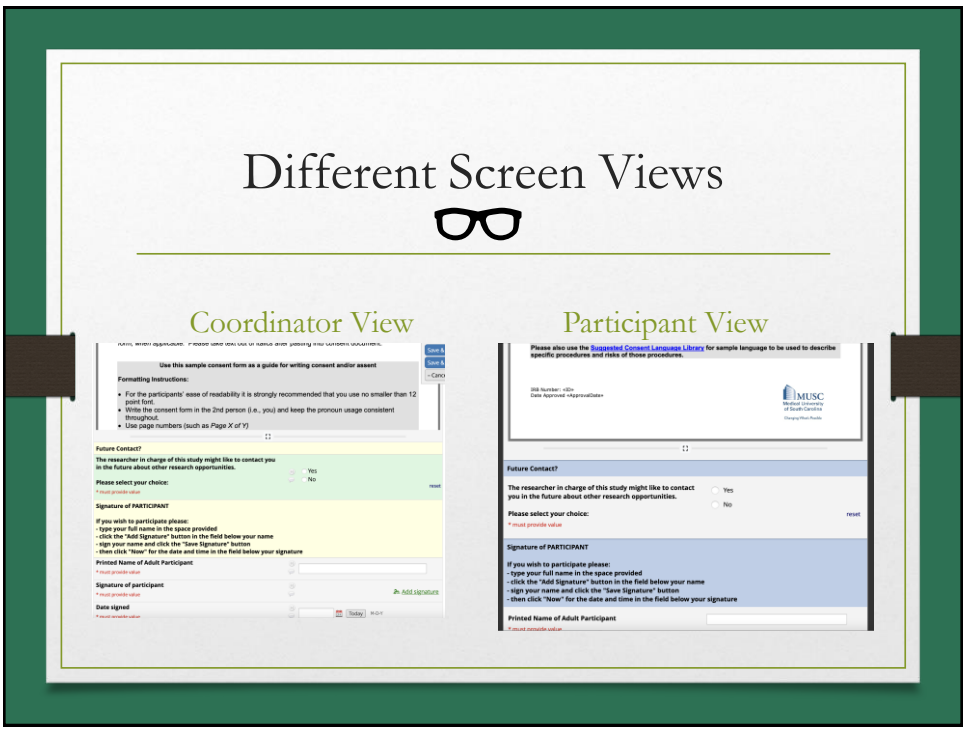


Helpful Tips

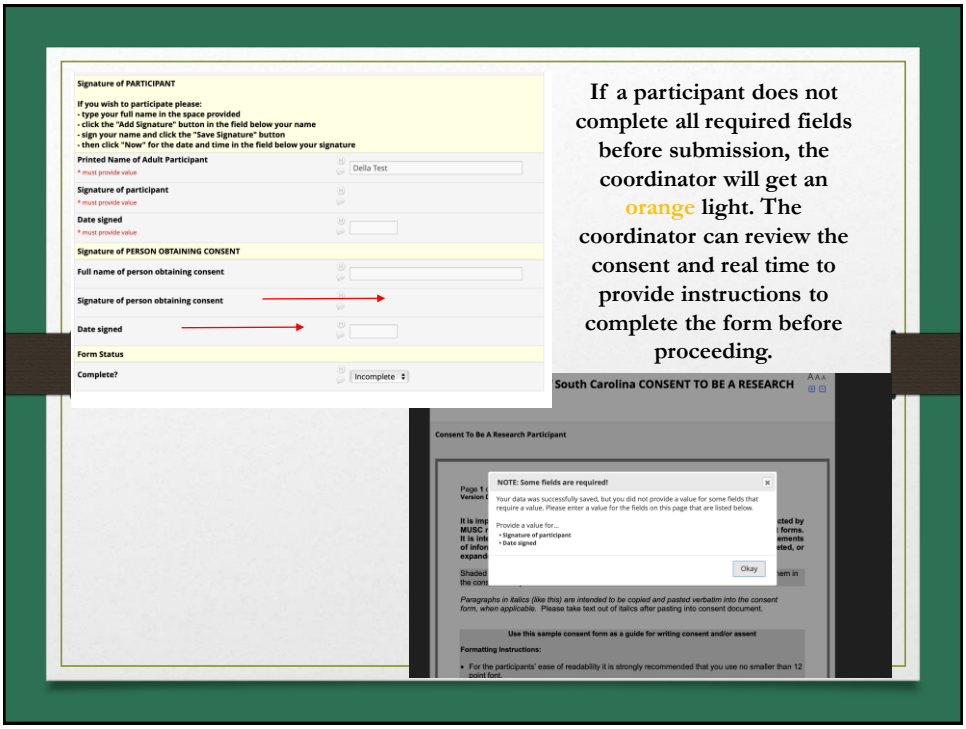
Add Study information to fillable fields for participants



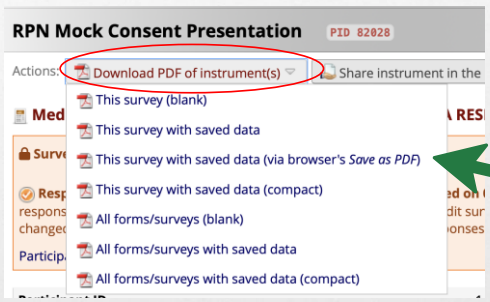

Participants can be skeptical of opening suspicious emails and clicking on links.
Today
RPN Stu...
Electronic PR... 11:26 AM
Please take this survey. Y...
macnich...
[no subject] 2/27/24
Thank you for your intere...
macnich...
mock consent t... 2/27/24
Please take this survey. Y...
Electronic PRN Consent 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
If the link above does not work, try copying the link below into your web browser:
https://redcap.musc.edu/surveys/?s=5VmXCVcFa7SrsChj
This link is unique to you and should not be forwarded to others.


Different Screen Views
Coordinator View
Participant View

Mock Consent Presentation Link



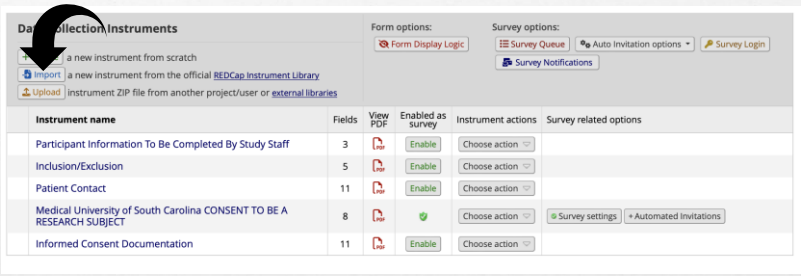
Signed Consent – Next Steps



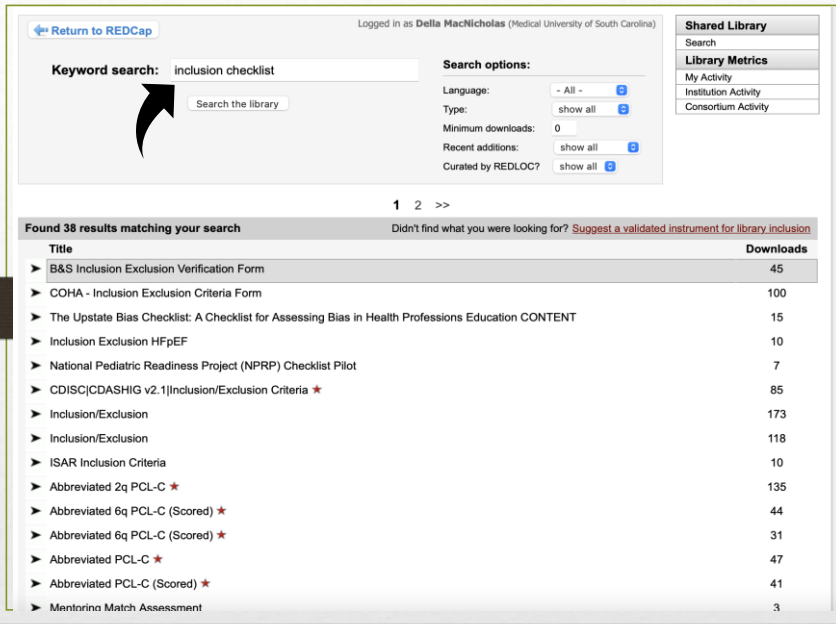
Note: There are multiple ways to share a signed consent. In this example, the coordinator downloads the fully signed consent directly from REDCap to email it to the participant. You must follow your Institutional, Regulatory and Study Team's guidelines for distributing the fully signed ICF.

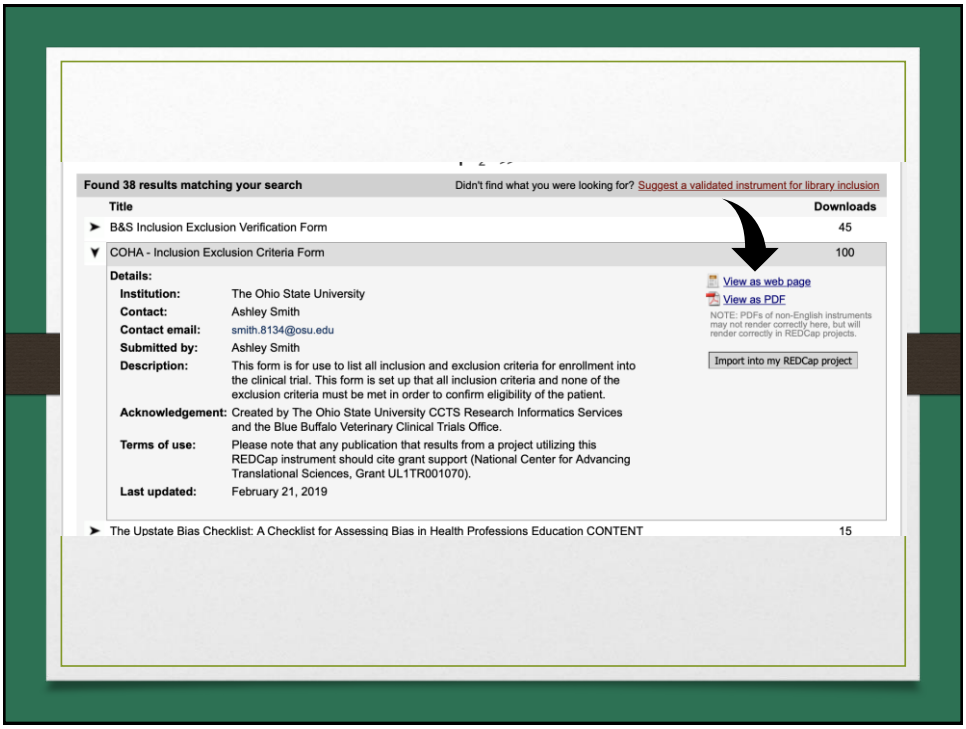
Optional Instruments – 101

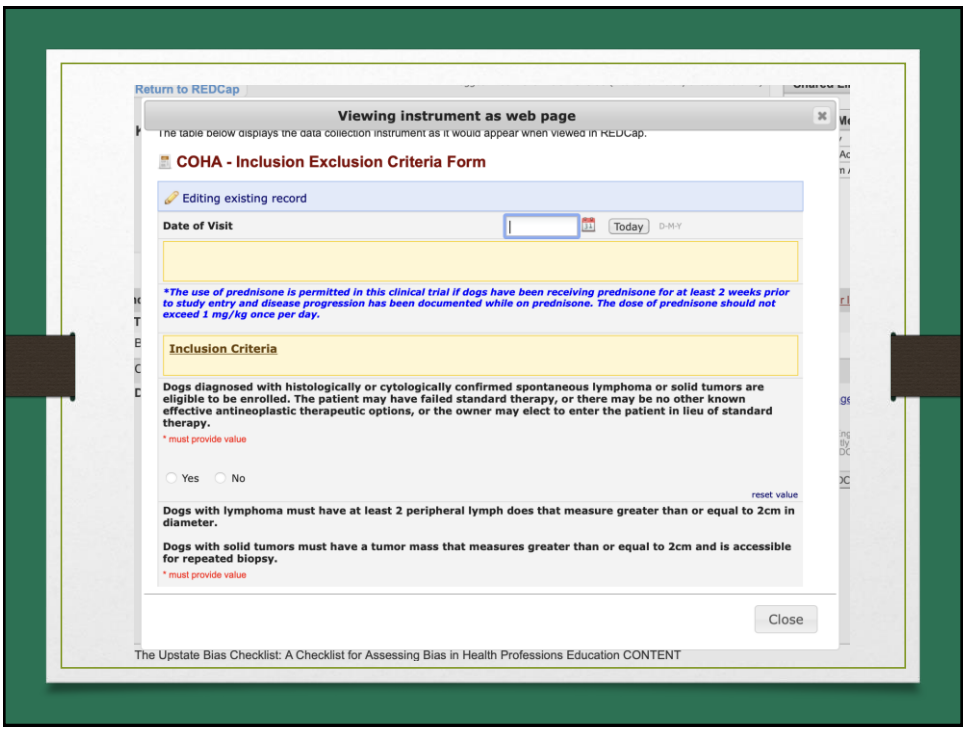
*Permissions are required to edit/add instruments to REDCap Projects

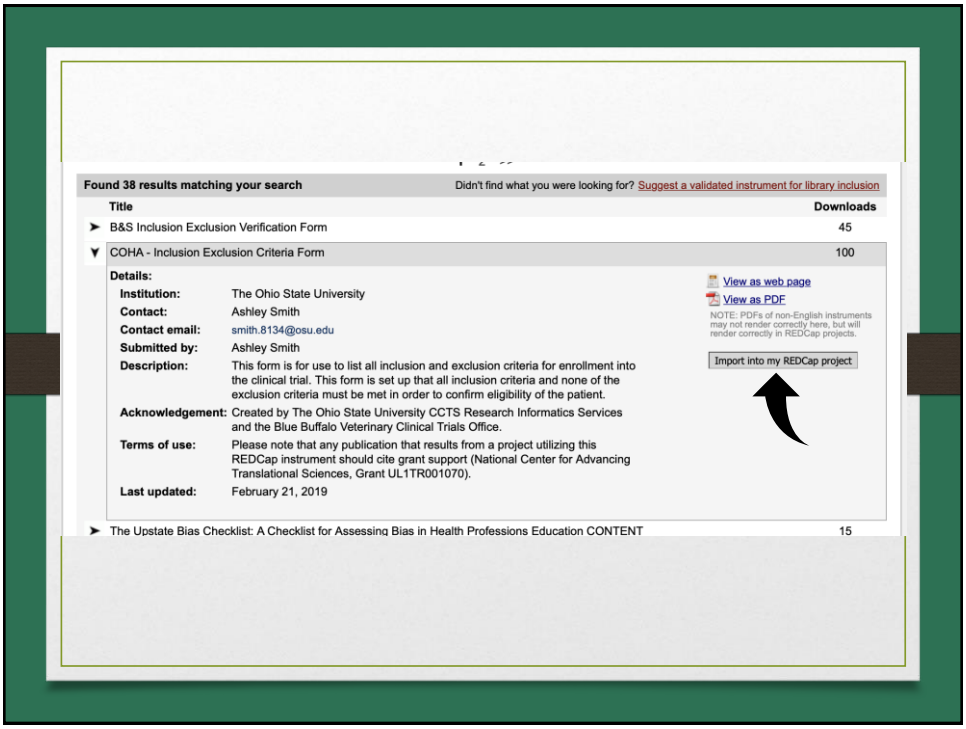


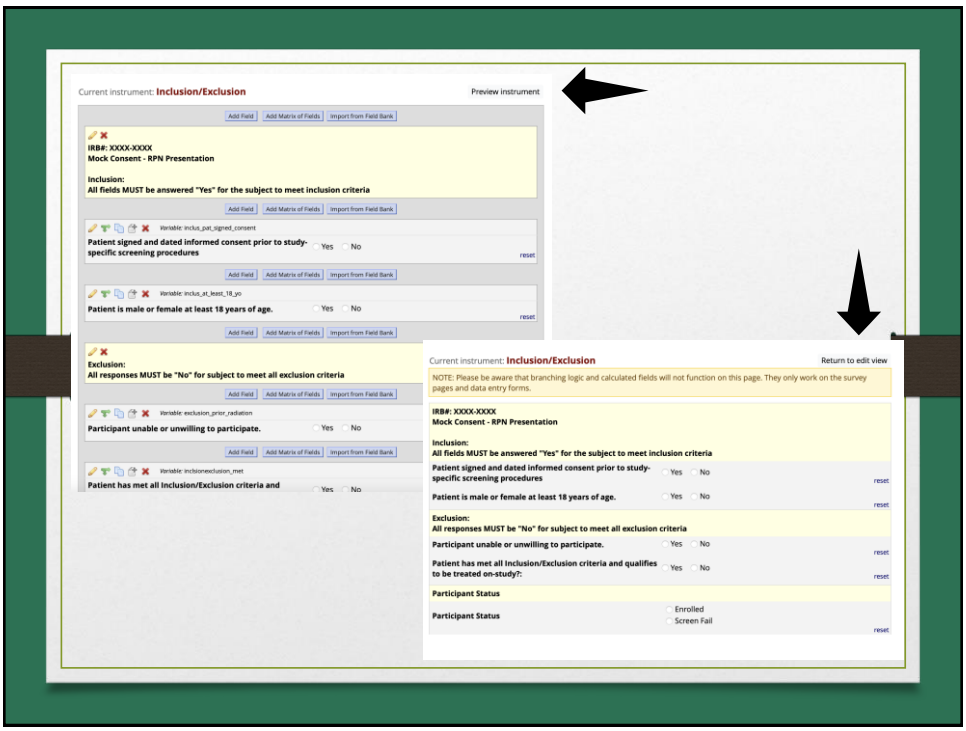
When building your eConsent in REDCap, you can access the REDCap Instrument Library to look for instruments that you can import and then edit for you specific project needs

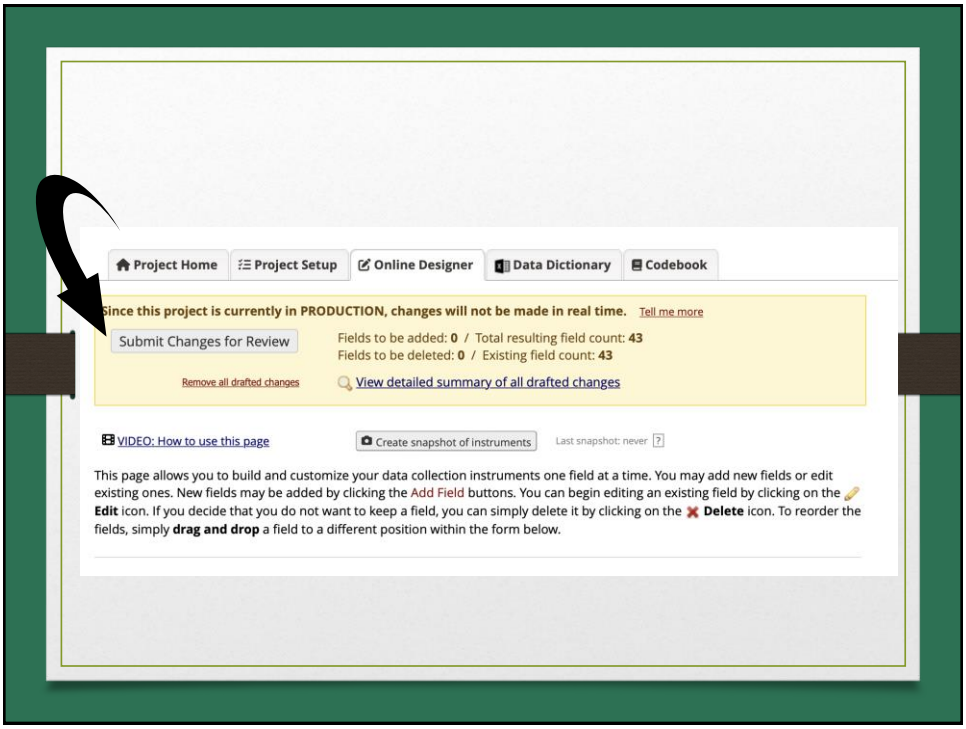



Found 38 results matching your search
Didn't find what you were looking for? Suggest a validated instrument for library inclusion
Title
Downloads
B&S Inclusion Exclusion Verification Form
45
COHA - Inclusion Exclusion Criteria Form
100
Details:
Institution: The Ohio State University
Contact: Ashley Smith
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 does 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
Close
The Upstate Bias Checklist: A Checklist for Assessing Bias in Health Professions Education CONTENT


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


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
Patient signed and dated informed consent prior to study-specific screening procedures
Patient is male or female at least 18 years of age.
Exclusion:
All responses MUST be "No" for subject to meet all exclusion criteria
Participant unable or unwilling to participate.
Patient has met all Inclusion/Exclusion criteria and qualifies to be treated on-study?:
Participant Status
Enrolled
Screen Fail
Return to edit view



Section IV:

Discussion

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?

59

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?

60

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?

61

AVOIDING RECRUITMENT BIASES

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

62

Resources

BMC/BU Medical Campus:

- eConsent Tools and Guidance (this is live link) (https://www.bumc.bu.edu/crro/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)