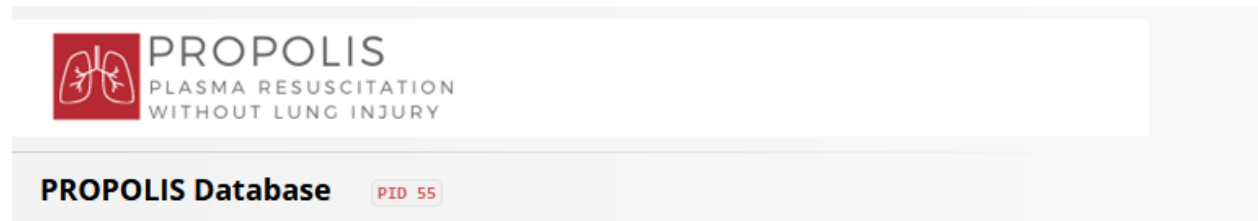


PROPOLIS REDCap Database How-to: Use REDCap for eConsent

- 1) Once you've assigned a participant a record and filled out the initial admission and inclusion and exclusion criteria, you can use REDCap to generate links for eConsent (if that is how the participant or the legally authorized representative (LAR) wishes to provide consent).
 - a. If you need to assign a record, see the training document called "Assigning IDs and Randomization".
- 2) Go to the "Consent" form:



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 ▾

Legend for status icons:

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

Record ID **7_3**

Admission ▾

Data Collection Instrument	Admission
Demographics	
Injury Information	
Inclusion Criteria	
Exclusion Criteria	
Consent	



PROPOLIS REDCap Database How-to: Use REDCap for eConsent

- 3) The Consent form walks you through several questions about consenting the patient, starting with whether the patient or LAR was approached for consent:
 - a. If the patient or LAR was not approached for consent (but was eligible for PROPOLIS and therefore has a record in the database), indicate why not, mark the record as complete, save the record, and then you are done with this record.


Consent

Data Access Group: [No Assignment] ?

Editing existing Record ID 7_3

Event Name: Admission

Record ID 7_3

Was patient or LAR approached for consent?  Yes
 No
* must provide value reset

LAR: legally authorized representative

3

Consent

Data Access Group: [No Assignment] ?

Editing existing Record ID 7_3

Event Name: Admission

Record ID 7_3

Was patient or LAR approached for consent? Yes
 No
* must provide value reset

LAR: legally authorized representative

Please indicate why patient or LAR was not approached for consent

Form Status

Complete?


3a

PROPOLIS REDCap Database How-to: Use REDCap for eConsent

- 4) If the patient (or LAR) has indicated that they are willing to consent into the PROPOLIS study, mark the appropriate radio buttons for:
 - a. Willing to consent or consent obtained (if not using eConsent)
 - b. Who will be or is providing consent

Consent

Data Access Group: [No Assignment] ?

 Editing existing Record ID 7_3

Event Name: **Admission**

Record ID	7_3
Was patient or LAR approached for consent? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>LAR: legally authorized representative</small>
Intent to consent indicated (or consent obtained) by the patient or LAR? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No
Who is/will be providing consent? <small>* must provide value</small>	<input checked="" type="radio"/> Patient <input type="radio"/> Legally authorized representative
Is eConsent needed? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No

← 4a


4b →

↑
5

- 5) If you're using eConsent, select "Yes" for the Is Consent needed question
 - a. If you're not using eConsent, select "No" and finish the rest of the consent data entry accordingly.

PROPOLIS REDCap Database How-to: Use REDCap for eConsent

- 6) Once eConsent has been marked as yes, additional fields will be generated by REDCap. The first is your name, which will be auto populated based on your REDCap username. As it says in the directions on REDCap, the next step is to hit the “Save and Stay” button in order for REDCap to generate the proper secure links for the consent form and the HIPAA form.

Was patient or LAR approached for consent? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>LAR: legally authorized representative</small>	reset
Intent to consent indicated (or consent obtained) by the patient or LAR? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Who is/will be providing consent? <small>* must provide value</small>	<input checked="" type="radio"/> Patient <input type="radio"/> Legally authorized representative	reset
Is eConsent needed? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Staff First Name <small>* must provide value</small>	<input type="text" value="Kara"/>	
Staff Last Name <small>* must provide value</small>	<input type="text" value="McMullen"/>	
In order to view links for the eConsent process which may be distributed to this participant, it is necessary to first save this instrument in order to generate the eConsent framework. You may use the "Save and Stay" option on this screen in order to complete this process and retrieve the links.		
eConsent Saved Date (mm/dd/yyyy)	<input type="text"/> M-D-Y	
eConsent Saved Time (24-hour clock)	<input type="text"/> H:M HH:MM	
HIPAA Saved Date (mm/dd/yyyy)	<input type="text"/> M-D-Y	
HIPAA Saved Time (24-hour clock)	<input type="text"/> H:M HH:MM	
Form Status		
Complete?	<input type="text" value="Incomplete"/> ▾	
<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Stay"/> ▾		
<input type="button" value="-- Cancel --"/>		

6

PROPOLIS REDCap Database How-to: Use REDCap for eConsent

- 7) When “Save and Stay” has been selected, REDCap processes this information and pulls up two links for the participant or LAR to use when providing eConsent.
 - a. You can email these links to the participant or LAR or, if you’re consenting in person and using eConsent, you can pull them up when you are with the participant or LAR and walk through the forms with them.
 - b. The information below the links will be autopopulated once the participant or LAR has signed the eConsent form.

The following links are ready to provide to participant:

Consent Form:

<https://redcap.iths.org/surveys/?s=GaletrqTBhahSijP>

HIPAA Form:

<https://redcap.iths.org/surveys/?s=dQLYaMvZkvG8hbGn>

eConsent Saved Date (mm/dd/yyyy)

 M-D-Y

eConsent Saved Time (24-hour clock)

 H:M
HH:MM

HIPAA Saved Date (mm/dd/yyyy)

 M-D-Y

HIPAA Saved Time (24-hour clock)

 H:M
HH:MM

PROPOLIS
PLASMA RESUSCITATION
WITHOUT LUNG INJURY

PROPOLIS REDCap Database How-to: Use REDCap for eConsent

- 8) When these links are selected, a new tab opens that provides your center's consent form or HIPAA for the participant or LAR to read through. At the bottom is an option for the participant to provide their first and last name and sign and date the consent form or the HIPAA form.

Study Staff Name:

Kara

McMullen

Date:

09-13-2021

Statement of Consent:

- All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
- If consent from a legally authorized representative is obtained, have the person obtaining assent document assent on the consent

Your signature documents your permission for you or the individual named below to take part in this research.

Name:

PROPOLIS

Participant

Date:

09-13-2021



Today

M-D-Y

Signature

* must provide value

[signature_2021-09-13_1206.png \(0.01 MB\)](#)

PROPOLIS REDCap Database How-to: Use REDCap for eConsent

- a. When they do this and select the “Next page” button, they will review the form and then certify that the information is correct.
- b. On the next page, they will be given an option to download a PDF of their consent or HIPAA form.



Resize font:
⊕ | ⊖

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

A screenshot of a PDF document viewer showing a consent form. The title is 'US Army Burn Center Consent'. The document is from the 'UNITED STATES ARMY INSTITUTE OF SURGICAL RESEARCH' and is titled 'CONSENT TO PARTICIPATE IN RESEARCH RESEARCH SUBJECT CONSENT FORM'. The specific study title is 'TITLE: Plasma ResuscitatiOn without Lung Injury (PROPOLIS)'. The protocol number is 'PROTOCOL NO.: CNTR-2020-001' and the IRB protocol number is 'IRB Protocol #20210893'. The sponsor is 'SPONSOR: Coalition for National Trauma Research (CNTR)'. The viewer interface includes a search bar, navigation arrows, a page indicator '1 of 6', a zoom control set to 'Automatic Zoom', and a 'Page 1' label.

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



PROPOLIS REDCap Database How-to: Use REDCap for eConsent

- 9) If you walk through eConsent with someone, don't forget to do both the consent form and the HIPAA form.
 - a. If you sent them links, be sure to check back in on their consent form in REDCap to make sure they finalized the process. If they didn't, their form won't be signed or dated. You will have to check in with them to get them to complete the consent process.

Event Name: Admission	
Record ID	7_4
Was patient or LAR approached for consent? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>LAR: legally authorized representative</small>
Intent to consent indicated (or consent obtained) by the patient or LAR? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No
Who is/will be providing consent? <small>* must provide value</small>	<input checked="" type="radio"/> Patient <input type="radio"/> Legally authorized representative
Is eConsent needed? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No
Staff First Name <small>* must provide value</small>	<input type="text" value="Kara"/>
Staff Last Name <small>* must provide value</small>	<input type="text" value="McMullen"/>
eConsent Saved Date (mm/dd/yyyy)	<input type="text" value="09-13-2021"/> M-D-Y
eConsent Saved Time (24-hour clock)	<input type="text" value="12:07"/> H:M HH:MM
HIPAA Saved Date (mm/dd/yyyy)	<input type="text" value="09-13-2021"/> M-D-Y
HIPAA Saved Time (24-hour clock)	<input type="text" value="12:11"/> H:M HH:MM
Form Status	
Complete?	<input type="text" value="Complete"/>
<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Stay"/>	
<input type="button" value="-- Cancel --"/>	

- 10) Once both sets of dates/times (for the Consent form and the HIPAA form) are logged and the record is showing "Complete," the eConsent process is done and you may exit the record in REDCap. If any information shown on the REDCap Consent form is incorrect, please contact Kara at mcmulk@uw.edu for technical assistance.