

# PROPOLIS REDCap Database How-to:

## Assign a Participant ID and Randomize a Participant

- 1) The record ID convention in PROPOLIS is “site\_id number”, where site is the PROPOLIS center site number and ID number is the number assigned at each site. **REDCap will not automatically assign an ID to a record for you**, so this is the first step.
  - a. Site numbers are:
    1. US Army Burn Center
    2. UAB
    3. UW
    4. VU
    5. UTMB
    6. UTSW/Parkland
  - b. For the ID number, use sequential numbers starting with 1. So, the first UAB patient screened will be numbered 2\_1. The third UTSW/Parkland patient screened will be 6\_3, and so on.
  - c. **It’s important to assign an ID and enter demographic and inclusion/exclusion criteria for every patient screened, even if they end up being ineligible or are eligible but do not consent.** We want to ensure that we can describe the population from which the PROPOLIS sample was drawn.
- 2) To enter a new patient, first select “Add/Edit Records.”
- 3) Enter the record ID (named based on the rules described above) into the blank field.

The screenshot displays the REDCap interface for the PROPOLIS Database. On the left sidebar, the 'Add / Edit Records' option is highlighted with a blue arrow and the number '2'. The main content area shows the 'Add / Edit Records' form. A yellow bar indicates 'Total records: 2'. Below it, there is a dropdown menu for 'Choose an existing Record ID' and a text input field for 'Enter a new or existing Record ID'. A blue arrow points to the text input field, and the number '3' is placed next to it.

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- 4) The grid that appears for each patient is called the Record Dashboard. On each patient's record dashboard, you can pick the following:
- The timepoint you want to enter information for.
  - The form you want to enter information for.



**PROPOLIS Database** PID 55

## 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. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

[Choose action for record](#)

### Legend for status icons:

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

Record ID 7\_1



4a

Admission

Data Collection Instrument	Admission
Demographics	
Injury Information	
Inclusion Criteria	
Exclusion Criteria	
Consent	
Randomization	
Admission Information	
Lab: Arterial Blood Gas	
Admission Lab: Blood Sample	
Ventilator Data	
Pre-BICU Intake/Output	
Research Lab Values	
Vital Signs	



4b

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- 5) For newly screened patients, the “Demographics” form is the first form to be completed. Click that radio button on the Record Dashboard and on the form, enter your site, your name and the date you screened the patient, their date of admission to the BICU, their date of birth, time of admission, age, and sex.



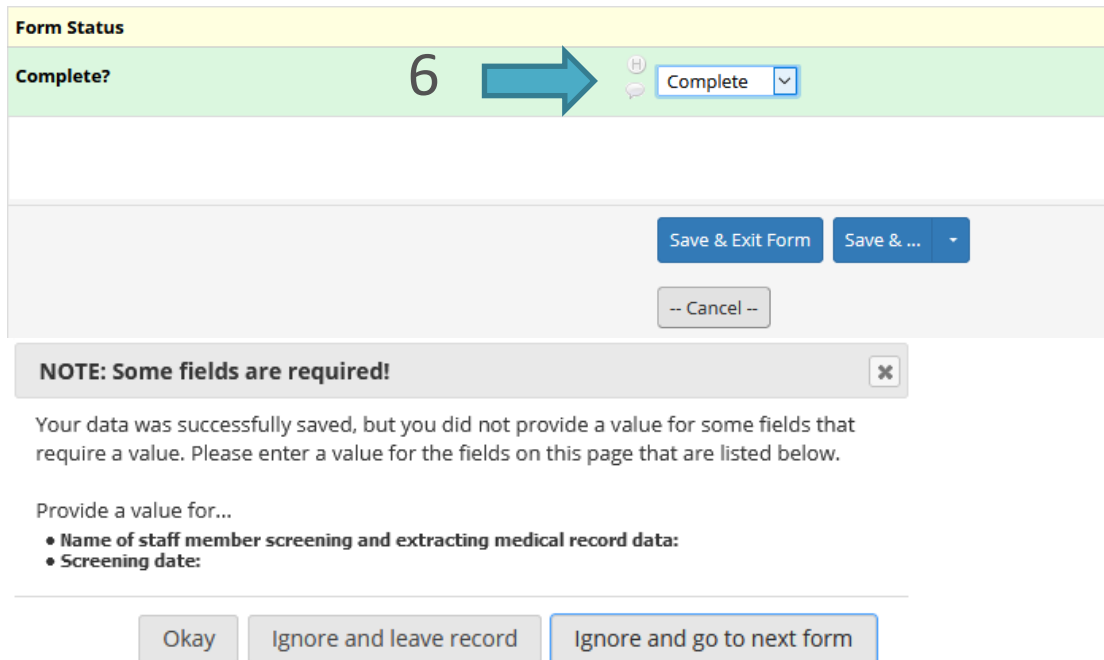
5

+ Adding new Record ID 7_1	
Event Name: Admission	
Record ID	7_1
PROPOLIS Site:	<input type="radio"/> US Army Burn Center - 1 <input type="radio"/> UAB - 2 <input type="radio"/> UW - 3 <input type="radio"/> VU - 4 <input type="radio"/> UTMB - 5 <input type="radio"/> UTSW/Parkland - 6 <input type="radio"/> Placeholder - 7
Name of staff member screening and extracting medical record data:	<input type="text"/>
Screening date:	<input type="text"/> Today M-D-Y mm/dd/yyyy
Screening time (24-hour clock):	<input type="text"/> Now H:M
Date of admission to BICU	<input type="text"/> Today M-D-Y mm/dd/yyyy
Date of birth	<input type="text"/> Today M-D-Y mm/dd/yyyy
Time of admission to BICU	<input type="text"/> Now H:M (24-hour clock)
Age at time of admission	<input type="text"/> (in years)
Sex	<input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Unknown

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- 6) Once the data is entered mark the record as “Complete” and hit “Save and Exit Form.” NOTE: you will not be able to proceed further until all reminders found in *red text* are addressed. If you try to save the form with reminder messages still present on the form you will see a message similar to the one below. Select “Okay” to resolve the reminder messages.



The screenshot shows a REDCap form interface. At the top, a yellow bar indicates the 'Form Status'. Below it, a green bar shows the 'Complete?' status with a large number '6' and a blue arrow pointing to a dropdown menu set to 'Complete'. Below the status bar, there are buttons for 'Save & Exit Form', 'Save & ...', and '-- Cancel --'. A grey box contains a 'NOTE: Some fields are required!' message with a close button. The message text reads: 'Your data was successfully saved, but you did not provide a value for some fields that require a value. Please enter a value for the fields on this page that are listed below.' Below the message, it says 'Provide a value for...' followed by a list of required fields: 'Name of staff member screening and extracting medical record data:' and 'Screening date:'. At the bottom, there are three buttons: 'Okay', 'Ignore and leave record', and 'Ignore and go to next form'.

**Form Status**

**Complete?** 6 → Complete

Save & Exit Form Save & ...

-- Cancel --

**NOTE: Some fields are required!**

Your data was successfully saved, but you did not provide a value for some fields that require a value. Please enter a value for the fields on this page that are listed below.

Provide a value for...

- Name of staff member screening and extracting medical record data:
- Screening date:

Okay Ignore and leave record Ignore and go to next form

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- 7) The “Injury Information” form is the next form on the Record Dashboard to be completed. Select that radio button and then fill in the information about the burn, including date, time, burn size, etiology, and non-thermal and inhalation injuries and then mark the form as “Complete” (same as in step #5, above) and save the form.

Record ID 7\_1

Admission

Data Collection Instrument	Admission
Demographics	<input checked="" type="radio"/>
Injury Information	<input type="radio"/>
Inclusion Criteria	<input type="radio"/>
Exclusion Criteria	<input type="radio"/>
Consent	<input type="radio"/>
Randomization	<input type="radio"/>
Admission Information	<input type="radio"/>



Editing existing Record ID 7\_1

Event Name: Admission

Record ID 7\_1

Date of burn (mm/dd/yyyy)  Today M-D-Y

Time of burn (24-hour clock)  Now H:M

Burn size, total (TBSA), %

Burn size, full thickness, %

Burn size, partial thickness, %

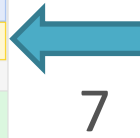
Burn etiology

Non-thermal injuries

Inhalation injury  Yes  No  Unknown

Expand

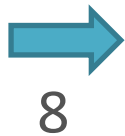
reset



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- 8) Next on the Record Dashboard is the “Inclusion Criteria” form. Select “Yes” or “No” to note the presence of each of the inclusion criteria. If one of the answers is no, the patient is **not eligible** for the study. Simply save the data in this form and the participant will have a status of excluded. There is no further data entry required—enter the form as “Complete,” hit the “Save” button, and you’re done.



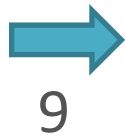
<b>Record ID</b>	7_1
<b>Inclusion Criteria: Each answer must be "yes" for the patient to be eligible for PROPOLIS</b>	
<b>If you say "no" to at least one exclusion criteria, the participant is not eligible for the study. Simply save the data in this form and the participant will have a status of ineligible. There is no further data entry required.</b>	
<b>If all of the inclusion criteria are present, the participant is eligible for the study.</b>	
<b>1. Age &gt;=18 years &amp; &lt; 65</b> <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
<b>2. Weight &gt; 40 kg (88.2 lbs)</b> <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
<b>3. Initial assessment of thermal injury size &gt;=20% TBSA</b> <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
<b>4. Admitted to the burn center and enrollable within 8 hours of injury</b> <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small> <small>Enrollable: Defined as treatment team believes there is enough time to get the study started before the 8th hour.</small>
<b>5. Expected to receive intravenous resuscitation fluids for at least 24 hours after injury</b> <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
<b>6. Expected to live &gt;24 hours after injury</b> <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
<b>Form Status</b>	
<b>Complete?</b>	<input type="text" value="Complete"/> <small>reset</small>
<b>Save &amp; Exit Form</b> <b>Save &amp; ...</b>	

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- 9) The next form on the Record Dashboard is “Exclusion Criteria.” If you say “yes” to at least one exclusion criteria, the patient is **not eligible** for the study. Simply save the data in this form and the patient will have a status of excluded. There is no further data entry required.

If all of the exclusion criteria are absent, the patient is **eligible** for the study.



Event Name: Admission	
Record ID	7_1
<b>Exclusion Criteria: Review the following criteria and do not enroll the patient if any apply. None of the answers can be "yes" in order for the patient to be eligible to participate in PROPOLIS.</b>	
If you say "yes" to at least one exclusion criteria, the participant is not eligible for the study. Simply save the data in this form and the participant will have a status of excluded. There is no further data entry required.	
If all of the exclusion criteria are absent, the participant is eligible for the study.	
<b>1. Chemical injury</b> * must provide value	<input type="radio"/> Yes <input checked="" type="radio"/> No reset
<b>2. Deep electrical injury</b> * must provide value	<input type="radio"/> Yes <input checked="" type="radio"/> No reset Deep electric injury: high voltage electric injury causing gross myoglobinuria (clinical diagnosis)
<b>3. Associated non-thermal injuries</b> * must provide value	<input type="radio"/> Yes <input checked="" type="radio"/> No reset Associated non-thermal injuries: defined as a requirement (because of traumatic injury) for blood transfusion, major intracavitary surgery (craniotomy, thoracotomy, laparotomy), angioembolization, or endovascular surgery during the first 24 hours after injury
<b>4. Decision not to treat due to injury severity or other factors</b> * must provide value	<input type="radio"/> Yes <input checked="" type="radio"/> No reset
<b>5. Patient already receiving plasma infusion or judged to be likely to require plasma infusion</b> * must provide value	<input type="radio"/> Yes <input checked="" type="radio"/> No reset
<b>6. Patient already receiving "rescue procedures"</b> * must provide value	<input type="radio"/> Yes <input checked="" type="radio"/> No reset Patient already receiving "rescue procedures": defined as albumin infusion, CRRT, TPE, or high-dose ascorbic acid
<b>7. Age ≥65 years or &lt; 18 years</b> * must provide value	<input type="radio"/> Yes <input checked="" type="radio"/> No reset
<b>8. Presence of anoxic brain injury that is not expected to result in complete recovery</b> * must provide value	<input type="radio"/> Yes <input checked="" type="radio"/> No reset
<b>9. Existence of any of the following pre-morbid conditions:</b>	
<b>1. Congestive heart failure (NYHA Class IV)</b>	<input type="radio"/> Yes

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10) If the participant is eligible for the study, the “Consent” form is the next form to be completed. For instructions for using eConsent, see the separate training form called “Use REDCap for eConsent”. This training form walks through how consenting without using eConsent.

On the consent form, you will be asked the following:

- If the patient or legally authorized representative (LAR) was approached for consent
- If consent was obtained, and if yes, who consent was obtained from (the patient or the LAR)
- Date and time of consent

If consent is obtained, the participant will be **randomized** to the study.

Editing existing Record ID 7\_1

Event Name: **Admission**

<b>Record ID</b>	7_1
<b>Was patient or LAR approached for consent?</b> <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>LAR: legally authorized representative</small>
<b>Was consent obtained from the patient or LAR?</b> <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No
<b>If consent obtained, who was consent obtained from?</b>	<input checked="" type="radio"/> Patient <input type="radio"/> Legally authorized representative
<b>Consent Date (mm/dd/yyyy)</b>	09-04-2021 <small>31</small> Today M-D-Y
<b>Consent Time (24-hour clock)</b>	13:35 <small>Now</small> H:M HH:MM
<b>Form Status</b>	
<b>Complete?</b>	Complete

Save & Exit Form Save & ...



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- d. If consent was not obtained because either the patient or the LAR were not approached or they were approached but declined, enter those details.
  - i. If not approached for consent, specify the reason why from the taxonomy provided.

Editing existing Record ID 7\_1

Event Name: Admission

Record ID 7\_1

Was patient or LAR approached for consent?  Yes  No  
\* must provide value LAR: legally authorized representative reset

Please indicate why patient or LAR was not approached for consent

Form Status

Complete?

LAR not available  
Missed patient/not able to approach in time  
Language barrier  
Family dynamics  
Other (please specify)

Save & Exit Form Save & ...

- ii. If approached for consent but consent was declined, specify the reason from the taxonomy provided.

Consent

Editing existing Record ID 7\_1

Event Name: Admission

Record ID 7\_1

Was patient or LAR approached for consent?  Yes  No  
\* must provide value LAR: legally authorized representative reset

Was consent obtained from the patient or LAR?  Yes  No  
\* must provide value reset

Choose the most important reason why patient or LAR did not consent

Form Status

Complete?

Too overwhelmed with injury  
Not interested  
Did not respond (approached for consent but timed out)  
Other (please specify)

Save & Exit Form Save & ...

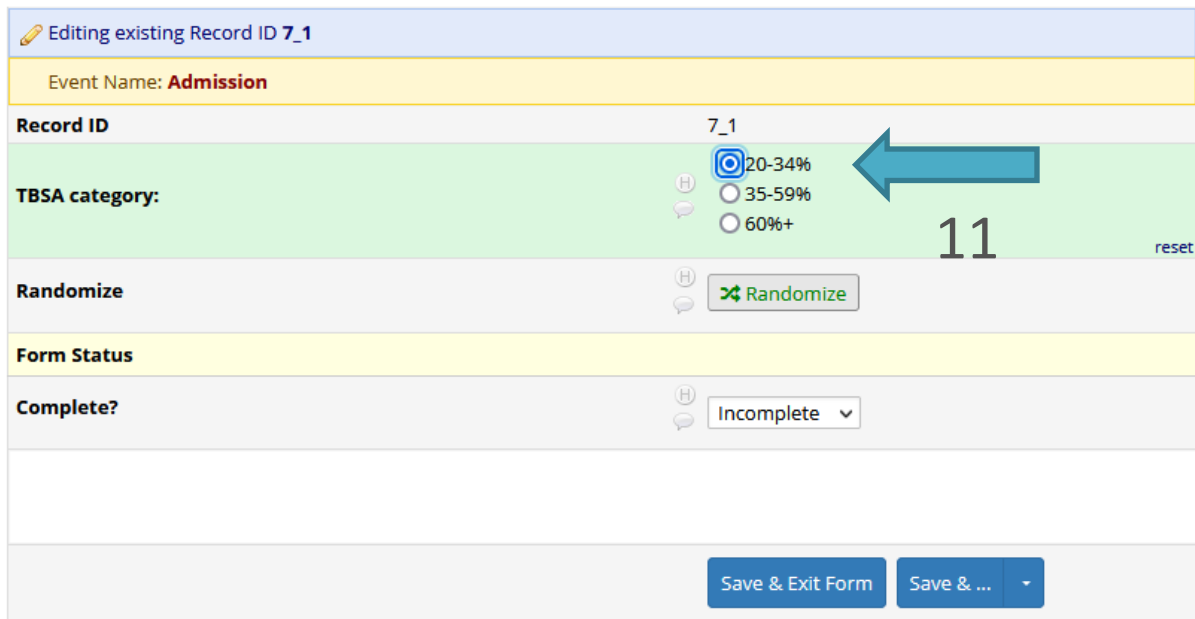
If consent is not obtained, the participant is **eligible but not randomized**. Simply save the data in this form and the participant will have a status of excluded. There is no further data entry required.

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11) If the patient is eligible and has consented (or a LAR has consented), it's time to randomize! Go to the "Randomization" form on the Record Dashboard. Because we're randomizing by TBSA category, you need to select which category the patient belongs to.

### Randomization



Editing existing Record ID 7\_1

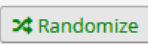
Event Name: **Admission**

**Record ID** 7\_1

**TBSA category:**

- 20-34%
- 35-59%
- 60%+

11 reset

**Randomize** 

**Form Status**

**Complete?**

Save & Exit Form Save & ...

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- 12) Once you've entered that, on the "Randomization" form select the "RANDOMIZE" button. The next screen will ask you to make sure the information about TBSA category and your site is correct. If site and TBSA category are correct, select the "Randomize" button:

➤ Randomizing Record ID "7\_1" ✕

Below you may perform randomization for Record ID "7\_1" on the field **Randomize** (*randomize*). Please note that the fields below will become permanently locked and uneditable on the data entry form once this record has been randomized.

Provide any missing values below for Record ID 7\_1, then click the Randomize button below.

**TBSA category:**

- 20-34%
- 35-59%
- 60%+

**PROPOLIS Site:**

- US Army Burn Center - 1
- UAB - 2
- UW - 3
- VU - 4
- UTMB - 5
- UTSW/Parkland - 6
- Data Center Testing Site - 7

reset reset




Randomize

Cancel

12

- 13) REDCap will then perform the randomization and assign the participant to a treatment group. Mark the "Randomization" form as complete and save the form. The form will always show the patient's randomized group, and you can also print the "Randomization" form for your paper records.

➤ Randomizing Record ID "7\_1" ✕

 Record ID "7\_1" was randomized for the field "**Randomize**" and assigned the value "**Control resuscitation**" (1).

Close