PRIDE: Guidelines for CRAs to Access the ECOG-ACRIN Systems for EASY Entry of PROs (EASEE-PRO)

The Participant Reporting Interface and Data Entry (PRIDE https://pride.stat.brown.edu) portal is the secure web interface that both participants and CRAs use to access EASEE-PRO. Thus PRIDE is the Front-end world facing portal while EASEE makes up the back-end systems for managing the data.

This document will attempt to outline the steps necessary to access the pride portal, assist in survey completion, and view monitoring reports.

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Overview

Note: ALL participants must be consented and registered to the EASEE-PRO component of an open CTEP approved protocol, using CTSU's OPEN registration system, before they can use EASEE-PRO. Note: EASEE-PRO registration occurs automatically, generally within 15 minutes, of a registration/randomization to a study in OPEN.

1. Consent and register the participant to the trial.

2. When completing the registration form in OPEN you will need to provide:

    a. A primary CRA contact email for each case (your email).

    b. For participants who will complete surveys online, a valid email address (patient's email).

    c. For all participants choosing mail administration (if applicable for the study), a participant contact sheet (PC) is faxed to the OEAU at the secure number provided on the PC form.

    Note: Some studies do not allow mail/paper participation.

3. OPEN will return the Subject ID and create a participant in EASEE.

    a. For a multi-study PRO, the case # in EASEE-PRO will generally be the study number + Subject ID (from OPEN):

    For example, if PROs are being collected from multiple parent studies (EA1131, EA5152, etc.) then EA1131 subject 1001 and EA5152 subject 1001 will be case # 11311001 and 51521001, resp.

    b. For a stand-alone or single study PRO, the EASEE ID and the OPEN Subject ID are the same.

    c. The participant's login name in EASEE will be set to their email address and their default account validation will be set to their birthdate.

    Note: if either their birthdate or email is typed incorrectly into OPEN, the participant will not be able to log into PRIDE. Please double check the spelling of all email addresses and the entry of the DOB.

4. To access and complete surveys on-line, participants only need to know their username (which is their email address), birthdate, and the address of the pride portal *(see participant instructions).*

    a. When activating their account, they will be asked to select a password and security question-answer and to enter some contact information.

5. Upon successful registration and randomization through OPEN, the participant will automatically be registered in EASEE-PRO and they will receive an account activation email at the address you entered during the registration process. The activation email simply directs them to the PRIDE web site. **Participants may access their account *at any time* using their email and password**. They do not need to wait to receive an email to log in and complete a waiting survey.

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CRA account and study access

1. You may use your account to check on study status, check participant calendars, view form completion/account activation, and when allowed by study design, assist participant and/or data enter questionnaire responses.

   a. Only Patients should complete questionnaires (Encourage participants to complete all questions and provide any factual information (i.e., health care info), but never decide for a patient what *should be* selected or guide them to responses *you think* they should select).

   b. If allowed by study design, you may provide participants onsite access to a web enabled device that they can use to complete questionnaires using the PRIDE portal.

   c. If allowed by study design, you may act as a scribe, reading questions to participants and recording answers and entering their responses using the PRIDE portal.

   d. If allowed by study design, participants may complete a questionnaire (generally only baseline) on paper, and you may data enter that questionnaire for them using the PRIDE portal.

2. CRAs may use their active CTSU-IAM account to access EASEE-PRO using the PRIDE portal.
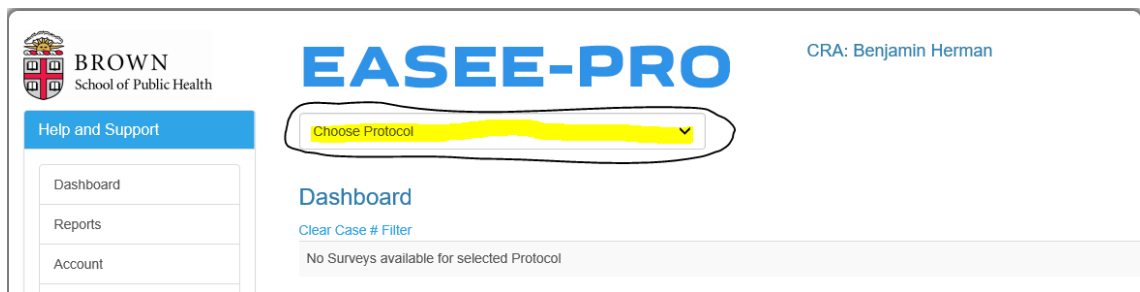   https://pride.stat.brown.edu/CRA-Login

   a. Select "CRA login" tab from the navigation bar.

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b. login using the familiar CTSU(IAM) interface and your CTEPID and password.
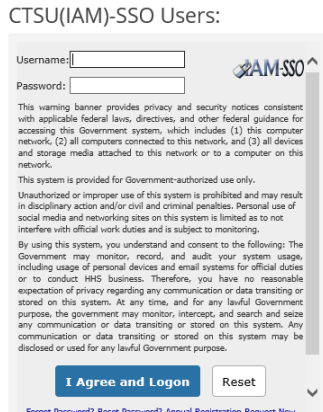
c. You will be presented with your dashboard page. Before anything can be displayed you need to select a study from the dropdown.

d. Dashboard displays only items that the logged in CRA may complete. **"Administrative"** presents non-participant surveys only (e.g., physicians/site staff); **"Participant"** lists only surveys that are to be completed by the participant *and* which are available for you to provide assistance (as outlined in this documents); and **"All"** presents all surveys awaiting completion for your site (for the selected study).
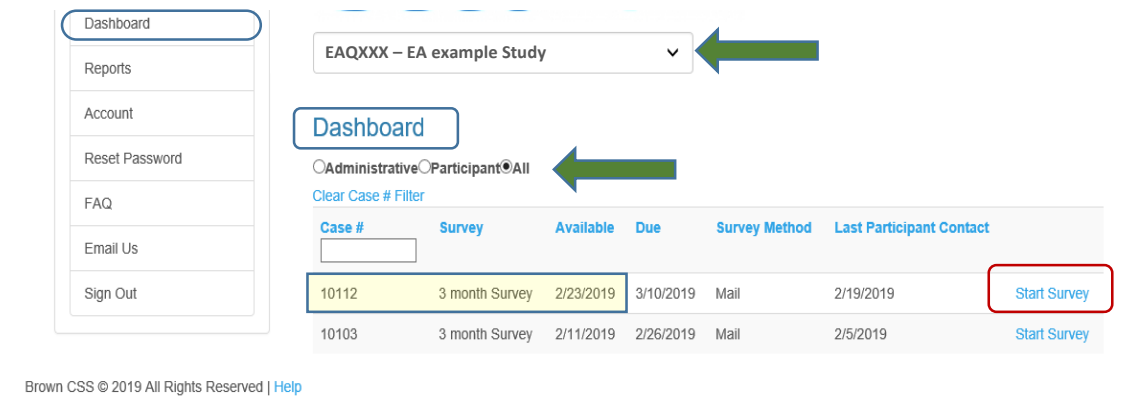
Note: the "Survey Method" above indicates "Mail" which means the patient has expressed a preference to receive the surveys by mail rather than online. However, if a survey appears in the dashboard, it means that the CRA may assist the participant completing the survey online. For example, you could read the participants the questions and enter the responses act as a (scribe) or you could data enter responses participants completed on paper.

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Instructions for sites providing participants with **web access**
Via computer, tablet, smartphone, etc., with a browser (such as IE, Chrome, Safari, etc.), and a quiet private location to complete the surveys.

1. Whenever possible, participants should login to the PRIDE portal using their own username and password to complete questionnaires. *(The first time Participants login they need to activate their account and update their contact information. This should be done as soon as possible after registration.)*

    a. Set the participant up in a quiet area on a web enabled device.

    b. Go to https://pride.stat.brown.edu

    c. Have the participant select Participant Login and login to their account with their email address (Note: it may take up to 15 minutes for the participant to appear in EASEE-PRO after registering in OPEN), and complete the survey as per the participant instructions.

Instructions for sites providing participants with **scribe support**
If allowed by the study, CRAs may read questions to participants and enter responses.

1. *(preferred)* Whenever possible, Scribe support should use the participants account.

    a. Set the participant up in a quiet area on a web enabled device, and have them login as in 1 above.

    b. Follow the participant instructions and assist the participant by reading screen prompts and entering responses.

2. Scribe support using CRA account:

    a. Set the participant up in a quiet area on a web enabled device.

    b. Login to your account as outlined in "CRA account and study access" above

    c. Search for the participants Case #, locate the correct survey, and select "Start Survey".

    d. Read screen prompts to participant and enter their responses.

    e. Be sure to signoff PRIDE and close your browser when the survey is completed

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Instruction for sites providing data entry assistance

If you do not have facilities for online data completion in your center and your study allows in clinic completion of surveys, the patient may be permitted to complete the questionnaires on <u>paper</u> and you may data enter the forms into EASEE-PRO using your account.

1. Ensure that the Case Id and Site ID are on each page of the paper copy.

2. Login to your account as outlined in "CRA account and study access" above

3. Search for the participants Case #, locate the correct survey, and select "Start Survey".

4. Enter the participant's responses as recorded on the paper form by selecting the matching response in the web screens.

5. Be sure to signoff PRIDE and close your browser when the survey is completed

6. Mark the paper form "File Copy" and, fax to the OEAU using our dedicated fax at 401-863-9635.

CRA reports:

When you log in you will have access to 3 monitoring reports: Protocol Status, Participant Status, and Participant Calendar.

1. Log into your CRA account (at to https://pride.stat.brown.edu):

2. Select Reports from the left navigation bar.

3. Select your study from the Protocol Drop-Down.

4. Click the report tab of the report you want.

Protocol Status

This report provides a summary of the number of cases enrolled at your site, how many are off study due to a status change (withdrawn, deceased, medically unable to continue, etc.), the number who have activated their accounts (provided us contact information) and the number of cases registered in the past 2 weeks.

EAQ152

Study	Step	Institution	Enrolled	Status Changed	Suppressed	On Study	Web Activated	Mail Activated	Web Pending	Mail Pending	Recent Reg (14)
⊞ EAQXXX	All	TOTAL	5	1	1	4	4	0	0	0	0

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Participant Status

This report provides a summary of the cases that have surveys due in the next 14 months.

Help and Support

- Dashboard
- Reports
- Account
- Reset Password
- FAQ
- Email Us
- Sign Out

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CRA: Pro-help
Pro-help@stat.brown.edu

EAQXXX – EA example Study

Available Reports

Protocol Status | Participant Status | Participant Calendar

Participant Status by Site

Surveys Due in the Next 14 Months

Institution	Participant	Activated	Next Survey	Due Date
CTSU-001	100002	Yes	T0 - Baseline	3/12/2017
CTSU-001	100100	Yes	T1 – Pre-Results	4/24/2017
CTSU-001	100122	Yes	T0 - Baseline	6/26/2017

Participant Calendar

This report allows you to see the participant calendar and form status.

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EAQXXX – EA example Study

Available Reports

Protocol Status | Participant Status | Participant Calendar

Participant #: 10000 - Activated

Status: Enrolled - 11/29/2017

Enrolled: 11/29/2017 5:21:35 PM

Enrolled By: Pro-Help - pro-help@stat.brown.edu

Site: CTSU001

Survey Calendar through 11/4/2019

Choose Participant

Participant Case #:10000

TimePoint	Available	Ends	Due	Received	Suppressed
T2 – Post Results	5/30/2018	12/1/2018	6/6/2018	6/4/2018	
T1 – Pre-Results	3/1/2018	12/1/2018	3/8/2018	3/6/2018	
T0 – Baseline	11/29/2017		12/9/2017	12/1/2017	

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