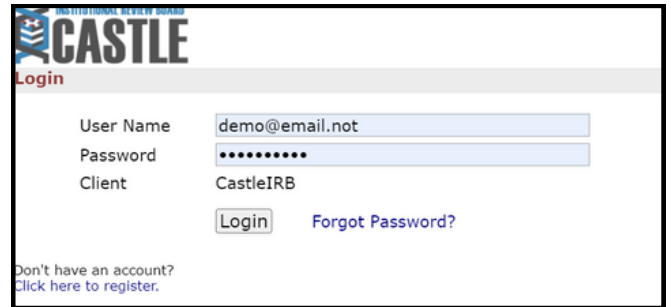


1. Portal Access

<https://castleirb.my.irbmanager.com/Login.aspx>

2. To create an Account

- Click on **"Click here to register"** under the **"Don't have an account?"** section.
- Enter your information.
- You will receive an email with instructions on setting a unique password.
- Log back into portal with your Username: [your email address] and unique password.



Note: All Principal Investigators must register for an account in order for their information to be uploaded into the system. You can use "New Contact Form" in the form to register your PI on their behalf.

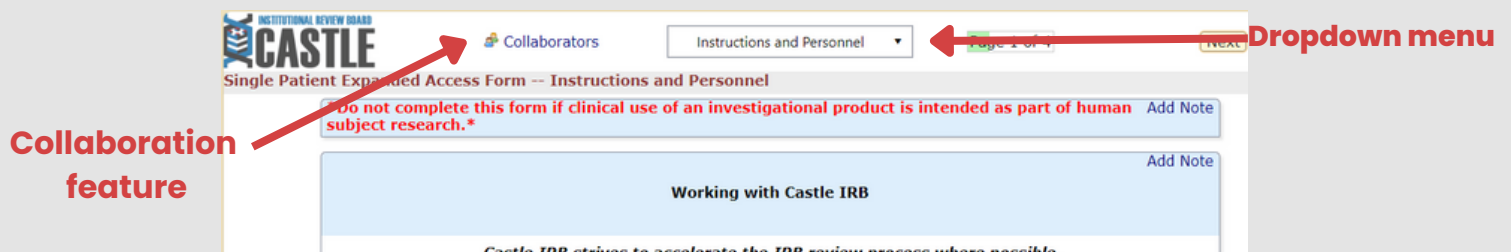
3. How to Complete Form

- Click on **"Start xForm"** in top left of the screen.
- Click on the link for **"Single Patient Expanded Access Application"**. Complete the application by clicking "Next" on each page.

If you do not have all the information for any page, you can bypass the error messages by using the dropdown menu in the top center of the form; select the next page you wish to view and continue to fill out the other pages.

You can always **"Save for Later"** using the button on the bottom of each page - if so, the next time you log in go to the link for **"Unsubmitted xForms"** in the center of your homepage.

Upon completion of application you will enter your password as your electronic signature. Click "Submit" to send your application to the IRB.



There is a "Collaborator" feature that allows you, site staff, or the Sponsor/CRO Project Manager to work on the form together. This feature is on the top center/left of the form. Add the collaborators email and give them access to view your submission form.

Our IRB team will contact you if they have any questions upon receipt of your submission. You will receive an **email notification** once the IRB has reached its decision with a link to your IRB documents.