
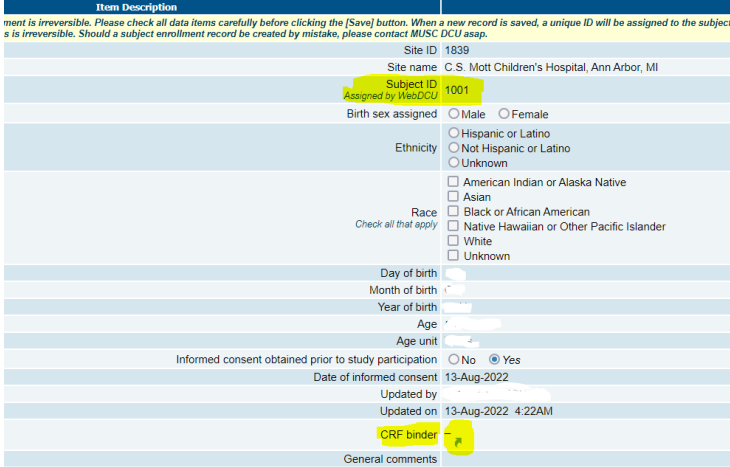


## P-ICECAP Enrollment and Randomization Instruction

Submission of **F102 Randomization** generates the subject's randomized treatment assignment. Please do not submit this form until you are ready to randomize. Once this form is submitted, the treatment assignment cannot be undone.

**The WebDCU™ 24 Hour randomization hotline can be used for after hour emergency issues. 1-866-450-2016**

**During business hours please contact Liz O'Donohue (843)-976-1129 or Sara Butler (843)-792-1599**

Step	Procedure	Notes/Troubleshooting
1.)Login	<p>A. Go to <a href="http://webdcu.musc.edu">http://webdcu.musc.edu</a></p> <p>B. Enter user name (full email address) and password, click [Login] button.</p> <p>C. Click on [PICECAP] tile</p>	<p>If you forgot your password, then click on the "Forgot Password" link at the bottom of the login screen to have a temporary password sent to your email address.</p>
2.)New Subject	<p>A. Select [Add New Subject] on the home screen.</p>  <p>B. If you have permissions at more than one site, select the appropriate site from the 'Site' drop-down box.</p> <p>C. Complete all items on form and click [Save Record].</p>	<p>If you do not see the [Add New Subject] button, you do not have the proper permissions or your site is not released to enroll subjects. For assistance during working hours, contact the Data Managers listed in [Emergency Help]. After business hours, please call the WebDCU Randomization hotline.</p> <p>Demographic information on the Subject Enrollment form does not need to be entered, these will be derived from F296 Demographics <b><u>after randomization.</u></b></p>
3.)Baseline	<p>A. When [Save Record] is selected, the subject ID will be assigned. Click on the green arrow at the bottom of the form to go to the subject's CRF Binder, where the Baseline CRFs will be posted.</p> <p style="text-align: center;">View: <a href="#">Subject Enrollment</a></p> 	<p>If a rule violation appears in red next to any question on the CRF after data saving, then click [Edit CRF] to make data corrections. Then click [Save Record] again and the [Submit CRF] button. For more on rule violations, refer to the Data Training video located on WebDCU Campus <a href="https://webdcu.musc.edu/campus/">https://webdcu.musc.edu/campus/</a></p>

	<p>B. Forms in the CRF Binder can be completed by clicking on the white paper icon next to each CRF name.</p> <p>C. After completing each CRF, click the [Save Record] button and then click the [Submit CRF] button.</p>	
<p>4.)Required CRFs for randomization</p>	<p>The CRFs listed below must be completed in order to determine eligibility for randomization:</p> <p>A. F101 Eligibility</p>	<p>On F101, all inclusion criteria questions must be answered ‘Yes’ and all exclusion criteria questions must be answered ‘No’ in order for the subject to be eligible for the study.</p> <p><b>Note: Any rule violations on this form will block randomization.</b></p> <p>If a rule violation appears in red next to any question on the CRF after data saving, then click [Edit CRF] to make data corrections. Then click [Save Record] again and the [Submit CRF] button. For more on rule violations, refer to the Data Training video located on WebDCU Campus <a href="https://webdcu.musc.edu/campus/">https://webdcu.musc.edu/campus/</a></p>
<p>5.)Eligible for randomization</p>	<p>A. If a subject is eligible for randomization, the randomization visit should be completed.</p> <p>B. Complete F102 Randomization, select [Save Record] <b>and</b> then the [Submit CRF] button to receive the treatment assignment.</p> <div data-bbox="228 1192 1162 1331" style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Subject meets all eligibility criteria <input type="radio"/> No <input type="radio"/> Yes</p> <p style="color: red; font-size: small;">[R] Subject must be eligible at the time of randomization.</p> <p style="color: red; font-size: small;">[R] F101 must be submitted.</p> </div>	<p>If the site states they are unable to see the treatment assignment, confirm the F102 has been submitted.</p> <p>For rule violations triggered on F102 Randomization, please review the Subject Enrollment form and/or F101 Eligibility for accuracy. Data on these forms can be edited and corrected to randomize <b>eligible</b> subjects.</p> <p>If F102 Randomization CRF is completed for an ineligible subject, randomization will be blocked and you will receive an error message. <b>If the WebDCU™ website is unavailable or if issues arise during randomization contact the data mangers listed in [Emergency Help] in WebDCU™. 1-866-450-2016</b></p>