

PRN Expulsion Log (EXP) [As Needed]

Note: this form is not participant facing. The staff member in contact with the participant when the expulsion/removal is reported should gather as many details as possible about the event, and use that information to complete this form.

To be used when a participant reports IVR coming out at any time that a follow-up CRF (FU2, FU3 or FU4) is not already completed (e.g. if a participant calls in to report ring expulsion or comes in for an interim visit). The goal is to capture details of the expulsion/removal to help understand the circumstances around the expulsion/removal.

<p>1. Has the vaginal ring been removed or expelled (intentionally or unintentionally) since the last visit or contact? <i>Check all that apply</i></p>	<p><input type="checkbox"/>₁ Yes, the ring was removed intentionally <input type="checkbox"/>₂ Yes, the ring came out unintentionally or accidentally</p>
<p>2. <i>[If Q1= 1]</i> How many times has the ring been removed intentionally since the last visit or contact?</p>	<p>___ times intentionally</p>
<p>3. <i>[If Q1 = 1]</i> Why was the vaginal ring removed? <i>Check all that apply</i></p>	<p><input type="checkbox"/>₁ It was uncomfortable <input type="checkbox"/>₂ It felt like it was falling out <input type="checkbox"/>₃ Participant wanted to show partner/ partner wanted to see it <input type="checkbox"/>₄ Partner asked participant not to wear it <input type="checkbox"/>₅ Participant wanted to clean it <input type="checkbox"/>₆ Participant was menstruating <input type="checkbox"/>₇ Participant wanted to have sex without it <input type="checkbox"/>₈ Participant was sick (e.g. diarrhea) and worried that it would be expelled <input type="checkbox"/>₉ Other (specify): _____</p>
<p>4. <i>[If Q1 = 2]</i> How many times has the vaginal ring come out unintentionally or accidentally since the last visit or contact?</p>	<p>___ times unintentionally</p>
<p>5. <i>[If Q1 = 2]</i> What caused the ring to come out?</p>	<p>Describe: _____ _____</p>
<p>6. Of the times mentioned above, what was the longest time that the ring was out?</p>	<p><input type="checkbox"/>₁ Less than 1 hour <input type="checkbox"/>₂ More than 1 hour but less than 3 hours <input type="checkbox"/>₃ More than 3 hours but less than 24 hours <input type="checkbox"/>₄ 24 hours or more <input type="checkbox"/>₅ Not sure</p>
<p>7. Was the ring re-inserted after it was removed or expelled?</p>	<p><input type="checkbox"/>₁ Yes <input type="checkbox"/>₂ No <input type="checkbox"/>₃ Unsure</p>
<p>8. Please note any further details surrounding the ring removal or expulsion, or surrounding the reinsertion.</p>	<p>_____ _____</p>

END OF CRF

CRF Completed By: _____ (initials) CRF Completion Date: ___ / ___ / _____ (dd/mm/yyyy)