

PRN Expulsion Log (EXP) [As Needed]

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

To be used when a participant reports film coming out partially or fully at any time other than a visit where the FU2 CRF is administered (i.e., in between visits/interim visit or at V6/V9). The goal is to capture details of the partial/full expulsion to help understand the circumstances around the expulsion.

1. Which film was expelled?	<input type="checkbox"/> 1 1 st film <input type="checkbox"/> 2 2 nd film
2. Was this a full or partial expulsion?	<input type="checkbox"/> 1 Partial <input type="checkbox"/> 2 Full <input type="checkbox"/> 3 Not sure, <i>specify:</i> _____
3. Where did the participant notice the film?	<input type="checkbox"/> 1 In the toilet <input type="checkbox"/> 2 On toilet paper <input type="checkbox"/> 3 In underwear <input type="checkbox"/> 4 Other, describe: _____
4. What was the participant doing when they saw the film?	<input type="checkbox"/> 1 Urinating <input type="checkbox"/> 2 Having a bowel movement <input type="checkbox"/> 3 Having sex <input type="checkbox"/> 4 Changing clothes <input type="checkbox"/> 5 Showering <input type="checkbox"/> 6 Other, describe: _____
5. Did the participant feel the film come out?	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 2 No (just saw the film)
6. What did the participant describe seeing when the film came out? E.g., size, shape, color, texture, etc.	_____ _____
7. What day did the participant first notice the film came out?	Date: _____ [DD] [MM] [YYYY]
8. Approximately what time of day was it when the participant noticed that the film had come out?	<input type="checkbox"/> 1 Morning (5am – 11:59am) <input type="checkbox"/> 2 Afternoon (12pm – 4:59pm) <input type="checkbox"/> 3 Evening (5pm – 9:59pm) <input type="checkbox"/> 4 Night (10pm – 4:59am)
9. In the six hours before noticing the film coming out, had the participant been doing any of the following activities?	<input type="checkbox"/> 1 Exercise or physical activity, describe: _____ <input type="checkbox"/> 2 Having sex <input type="checkbox"/> 3 Other, describe: _____
10. Please note any further details surrounding the film expulsion.	_____ _____

END OF CRF

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