



MATRIX-002, SBR Operational Guidance #2

Operational Guidance Category:

Clinical Procedures Pharmacy Laboratory Other, specify: SBR

Brief Description: Implementation of the PRN Expulsion Log

The purpose of this Operational Guidance document is to clarify operational matters related to the use of the recently issued PRN Expulsion Log in MATRIX-002 (*See "MATRIX-002 Data Communique #1_SBR CRFs_22Feb2024"*). The following provides instructions on the implementation of this form.

- New prompt in REDCap in the FU3 and FU4 forms:** Existing questions in FU3 (#8a) and FU4 (#8a) ask about occurrences of partial/full expulsion. If a participant responds that they have had this experience, a prompt will appear in the REDCap platform to prompt the completion of the PRN expulsion log. However, if data collection is being done on a paper form, there is not a specific prompt and interviewers should be made aware that they will need to flag this occurrence and independently initiate the PRN Expulsion Log as appropriate.
- Updating visit checklists:** Any expulsion reported at a visit where the FU2 form is administered will be best captured in the FU2 form. However, if an expulsion is reported at any other timepoint (participant phone call, interim visit, V6/V9) or prompted by a question on the FU3 or FU4 forms, the PRN Expulsion Log should be used. To help this be done consistently, the team recommends editing study checklists for Interim Visits, V6, and V9 to include this as an optional item to be completed.
- Avoiding duplicate reporting of expulsions:** Each expulsion should only be captured once, on either the FU2 form OR the PRN Expulsion log. The question in the FU2 is phrased to ask about experiences "since your last visit/contact", which should indicate to the participant that we are asking about new reports. If multiple incidents are reported, please gather more information from the participant to be able to determine if a new report matches an expulsion that has already been documented.

Operational Guidance memos, once signed, must be distributed to MATRIX sites via email. Sites are responsible for ensuring that appropriate staff review and understand the content of each memo and file the memo with their essential documents. Operational Guidance memos must also be posted to the appropriate MATRIX webpage. As per SSP section 13, the memos are official study documentation and will be considered an official part of the MATRIX SSP Manual. The Operational Memo becomes effective the date it is signed.

DocuSigned by:

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3/8/2024

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Date