Protocol ID: _____

Study Name: _____

Site: _____

Event Name: _____

Event Date: _____

Study Subject ID:_____

Interviewer Name:_____

Interview Date:_____

FRM046 DMP Prior to locking - v1.0

Section Title: Prior to locking
Instructions:

PI signitatures

How are PI signitatures being recorded?   ○ OpenClinica ○ Paper or filenote

Database lock

Is an interim lock required?   ○ Yes ○ No

Requirements for interim lock

☐ Case Report Form (CRF) completion review

☐ Data query review

☐ Automatic edit check (AEC) review

☐ Source data verification (SDV) review

☐ Serious adverse event (SAE) reconciliation

☐ Coding

☐ PI Signature

☐ Authorisation to lock obtained from all parties

Requirements for hard lock (the following is always required for a hard lock: Source data verification (SDV) review, PI Signature, Authorisation to lock obtained from all parties)

☐ Case Report Form (CRF) completion review

☐ Automatic edit check (AEC) review

☐ Serious adverse event (SAE) reconciliation

☐ Coding

SAE reconciliation

Is SAE reconciliation required?   ○ Yes ○ No

SAE reconciliation plan

Protocol ID: _____

Study Name: _____

Site: _____

Event Name: _____

Event Date: _____

Study Subject ID:_____

Interviewer Name:_____

Interview Date:_____

Section Title: Revision history
Instructions:

Revision date *	Revision notes *	Amendment type *	Authorised by
		○ (select) ○ Minor ○ Major	