REFRAMED SAE-SUSAR report form

SAE ID	PATIENT ID	DATE OF ONSET	ADVERSE EVENT / ADVERSE REACTION	RANDOMISATION DATE	STUDY STATUS	TIME AFTER RANDIMISATION	EVENT/ REACTION	CLINICAL ACTION

REFRAMED Trial office phone: 023 8059 5077

Participant study ID: SAE/SUSAR ID:

Once a SUSAR or SAE has been identified, please **complete sections 1-5** on this form with as much information as possible before emailing it (encrypted) to the Trial Team: reframed@soton.ac.uk within 24 hours of knowledge of the event.

Please update all sections as information becomes available and complete **sections 6-8** before resending the forms at the follow-up reporting period **within 5 days of sending the initial or previous report** until the SUSAR has been resolved or a decision for no further follow up has been taken (if further follow up is required please copy and use the last page if this form.

1. Details of the study					
Full title:	REFRActory depression - Mechanisms and Efficacy of Dialectical Behaviour Therapy				
Study Centre (Trust):					
R&D No:					
Ethics No:	11/SC/0146				
UKCRN No:	10234				
ISCRTN No:	ISRCTN85784627				
RGO ID Southampton	8014				

2. Details of participant affected by SAE/SUSAR			
Study ID:	Initials:	DOB (dd/mm/yyyy)	Gender:

Disease history: prior diseases suffered by the participant not being treated by the current study

Disease name	Start Date	End Date	Continuing (yes/no/unknown)

Drug history: ALL medication taken within last 6 months

Drug name	Start Date	End Date

3. Reaction Details	
Country of origin:	

Reaction/SAE	Outcome (recovered, recovering, not recovered, fata, unknown)	Start Date	End date

Narrative: detailed description of SAE/SUSAR	
Setting (e.g. hospital, out-patient clinic, home):	
Body sites(s):	
Diagnosis (if available)	
Other information (including severity):	

Seriousness

□ Death □ Life threatening □ Hospitalisation □ Disabling

□ Congenital anomaly □ Other

Details of medical tests undertaken relevant to SAE/SUSAR

Test	Result	Unit	Test Date

4. Action Taken at 24 h (initial reporting interval)

5. Details of Principal Investigator at this site writing the initial report details (at 24 h)		
Name:		
Job title/Role in Study:		
Contact Address:		
Email Address		
Telephone No:		
Signature		Date:

Additional Information	
Section Number	Further Information

6. Update on outcome assessed at follow-up reporting interval (within 5 days of the initial or previous report)*
□ Resolved □ Ongoing □ Died
*Give details of outcome indicated (including post-mortem details in case of death)

7. Details of any further action taken since first report

8. Details of Principal Investigator or delegated physician at this site writing the follow-up report (if different from Section 5)		
Name:		
Job title/Role in Study:		
Contact Address:		
Email Address		
Telephone No:		
Signature		Date: