

ANNUAL PROGRESS REPORT

To be completed in typescript and submitted to the Social Care REC by the Chief Investigator. For questions with Yes/No options please indicate answer in bold type.

1. Details of Chief Investigator

Name:	
Address:	
Telephone:	
E-mail:	
Fax:	

2. Details of study

Full title of study:	
Social Care REC reference number:	
Date of favourable ethical opinion:	
Sponsor:	

3. Commencement and termination dates

Has the study started?	Yes / No
<i>If yes, what was the actual start date?</i>	
<i>If no, what are the reasons for the study not commencing?</i>	
What is the expected start date?	
Has the study finished?	Yes / No

<i>If yes, complete and submit “Declaration of end of study” form, available at www.screc.org.uk</i>	
If no, what is the expected completion date? <i>If you expect the study to overrun the planned completion date this should be notified to the Social Care REC for information.</i>	
If you do not expect the study to be completed, give reason(s)	

4. Site information

Do you plan to increase the total number of sites proposed for the study? <i>If yes, how many sites do you plan to recruit?</i>	Yes / No
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5. Recruitment of participants

In this section, “participants” includes those who will not be approached but whose data will be studied.

Number of participants recruited:	<i>Proposed in original application: Actual number recruited to date:</i>
Number of participants completing study:	<i>Proposed in original application: Actual number completed to date:</i>
Number of withdrawals from study to date due to:	
(a) withdrawal of consent	
(b) loss to follow-up	
(c) death (where not the primary outcome)	
Total study withdrawals:	
Have there been any serious difficulties in recruiting participants?	Yes / No
<i>If Yes, give details:</i>	
Do you plan to increase the planned recruitment of participants into the study? <i>Any increase in planned recruitment should be notified to the Social Care REC as a substantial amendment for ethical review.</i>	Yes / No

6. Safety of participants

Have there been any related and unexpected significant adverse events (SAEs) in this study?	Yes / No
Have these SAEs been notified to the Committee? <i>If no, please submit details with this report and give reasons for late notification.</i>	Yes / No /Not applicable
Have any concerns arisen about the safety of participants in this study? <i>If yes, give details and say how the concerns have been addressed.</i>	Yes / No

7. Amendments

Have any substantial amendments been made to the study during the year?	Yes / No
<i>If yes, please give the date and amendment number for each substantial amendment made.</i>	

8. Serious breaches of the protocol

Have any serious breaches of the protocol occurred during the year?	Yes / No
<i>If Yes, please enclose a report of any serious breaches not already notified to the Social Care REC.</i>	

8. Other issues

Are there any other developments in the study that you wish to report to the Committee?	Yes / No
Are there any ethical issues on which further advice is required?	Yes / No
<i>If yes to either, please attach separate statement with details.</i>	

9. Declaration

Signature of Chief Investigator:	
Print name:	
Date of submission:	