

PROVE on-site monitoring checklist

1. SITE FILE – section 1

Documents in File	Latest Approved Version	Version in site file
GP/Consultant Information Sheets - GP letter	1.1	
Letter of invitation - Main Study	1	
Initial Approach Letter - Main Study	1	
Reply Slip - Main Study	2.1	
Letter of invitation - Qualitative Study	1	
Reply Slip - Qualitative Study	2.1	
Letter to non-respondents - Qualitative Study	1	
Letter to non-respondents	3	
Participant Diary 1	2	
Participant Diary 2	2	
Participant Consent Form: Main Study	1.2	
Participant Consent Form: Qualitative Study	2.1	
Participant Information Sheet: Qualitative Study	1	
Participant Information Sheet: Main Study	6	
Protocol	4	
Re-consent form	1	
letter to participants from GPs	1	
Recruitment Letter - practice recruitment letter	0.1	
Prove study Information Flyer - GP office flier	0.1	
Latest Amendment	8	

2. SITE FILE – section 2

Documents	Complete	Need updating
Delegation Log		
CVs		
GCP certificates (PI and everyone who is consenting)		
Copy of Participant consent forms		
Screening logs		
Change of Status Log		
AE/SAE		

3. Participant visit Monitoring

	Assessment	Treatment Session
Appropriate equipment used		

Protocol procedures followed		
Documentation completed		

NOTES:

SITE

Attendance Signatures

Date

NAME	SITE ROLE	Signature