

## PLORAS Summary of Substantial Amendments

Number	Details	Date	Approved?	Category
1	<b>Summary:</b> We sought approval for modifying our poster (document 1b) into a smaller version. This was to be used as an advertisement in appropriate publications, e.g. Stroke News magazine, national press, etc.  NB: There is no acknowledgement letter/favourable opinion letter from our REC for the advert - we later learned that it can be submitted as a minor amendment as it is a reduced size version of the approved poster.		N/A	N/A
	1e - PLORAS Advert			
2	<b>Summary:</b> We sought approval for a letter template to be sent to potential participants, as an initial contact to establish whether they would consider taking part in the study. The letter would be sent by research practitioners at local sites, with a stamped addressed/postage paid envelope to avoid the patient incurring any costs.		No	
	1d - PLORAS Invitation for Trust or GP Patients V2 November 2013			
	Notice_of_Amendment_2			
	13-LO-1515_Substantial_Amendment_2_Acknowledgement_Letter			
	13-LO-1515-Substantial_Amendment_2_Unfavourable_Opinion_Letter			
3	<b>Summary:</b> We sought approval for changes made following feedback for Substantial Amendment 2 from the ethics committee: <ul style="list-style-type: none"> <li>• Simplified the letter.</li> <li>• Created a picture version of the letter.</li> <li>• Added a statement offering assurances to those patients who choose not to take part.</li> <li>• Added the names of contact persons.</li> <li>• Added text highlighted in yellow on document 1d.</li> </ul>		Yes	
	1d - PLORAS Invitation for Trust or GP Patients V3 February 2014	Feb 2014		
	1d-P - PLORAS Invitation for Trust or GP Patients V1 February 2014	Feb 2014		

	Notice_of_Amendment_3	Feb 2014		
	13-LO-1515_Substantial_Amendment_3_Acknowledgement_Letter	Feb 2014		
	13-LO-1515_Substantial_Amendment_3_Acknowledgement_Letter_Old	Feb 2014		
	13-LO-1515-Substantial_Amendment_3_Favourable_Opinion_Letter	Feb 2014		
	13-LO-1515-Substantial_Amendment_3_Favourable_Opinion_Letter_Old	Feb 2014		
4	<b>Summary:</b> We sought approval for several changes. Some changes were made at the request of our external recruiting sites, to facilitate their recruitment procedures. Others were initiated internally by the PLORAS Research Team, partly again to facilitate smoother recruitment and testing procedures and, importantly for the welfare of our participants, to simplify and reduce what can be burdensome paperwork for participants with communication difficulties.  See supporting documents for all changes: <ul style="list-style-type: none"> <li>• Covering Letter for Substantial Amendment 4</li> <li>• PLORAS Version Control 23.12.2014</li> </ul>		Yes	
	1d - PLORAS Invitation for Trust or GP Patients V4 December 2014	10/12/2014		
	1d-P - PLORAS Invitation for Trust or GP Patients V2 December 2014	10/12/2014		
	2__PLORAS Participant Information Sheet V3 November 2014	03/11/2014		
	2-C__PLORAS Consultee Information Sheet V3 November 2014	03/11/2014		
	2-P__PLORAS Participant Information Sheet V3 November 2014	03/11/2014		
	2S__PLORAS Participant Information Sheet External+V3 November 2014	03/11/2014		
	2S-C__PLORAS Consultee Information Sheet External+ V3 November 2014	03/11/2014		
	2S-P__PLORAS Participant Information Sheet External+ V3 November 2014	03/11/2014		
	3__PLORAS Participant Screening Questionnaire and Initial Consent V3 November 2014	03/11/2014		
	3-P__PLORAS Participant Screening Questionnaire and Initial Consent V3 November 2014	03/11/2014		
	3E__PLORAS Participant Screening Questionnaire External V3 November 2014	03/11/2014		
	3E-P__PLORAS Participant Screening Questionnaire External V3 November 2014	03/11/2014		
	3S__PLORAS Participant Screening Questionnaire External+ V3 November 2014	03/11/2014		
	3S-P__PLORAS Participant Screening Questionnaire External+ V3 November 2014	03/11/2014		
	4__PLORAS Participant Information and Consent V3 November 2014	23/12/2014		
	4-C__PLORAS Declaration V3 November 2014	23/12/2014		
	4-P__PLORAS Participant Information and Consent V3 November 2014	03/11/2014		
	4E__PLORAS Consent External V3 November 2014	03/11/2014		
	4E-C__PLORAS Declaration External V3 November 2014	03/11/2014		

	4E-P__PLORAS Consent External V3 November 2014	03/11/2014		
	4S__PLORAS Consent External+ V3 November 2014	03/11/2014		
	4S-C__PLORAS Declaration External+ V3 November 2014	03/11/2014		
	4S-P__PLORAS Consent External+ V3 November 2014	03/11/2014		
	PLORAS_Protocol_V3_November_2014	03/11/2014		
	Notice_of_Amendment_4	05/01/2015		
	Covering_Letter_for_Substantial_Amendment_4	12/01/2015		
5	<b>Summary:</b> We sought approval for a letter template for contacting previous participants in our study who answered 'yes' to the following question on the consent form: 'The PLORAS Research Team can contact me in future about taking part in other studies.' The letter is sent to participants (who answered 'yes' to the above question) who we think might be suitable for other studies our collaborators are running. The collaborating institutions we send this on behalf of will include (but not be limited to) universities, hospitals, and charities. They will have their own ethical approval for their study.		Yes	
	1f__PLORAS Other Studies Invitation Letter V1 January 2016	08/01/2016		
	Notice_of_Amendment_5	08/01/2016		
	13-LO-1515_SA5_REC_Acknowledgement	01/02/2016		
	13-LO-1515_SA5_REC_Favourable_Opinion	10/02/2016		
6	<b>Summary:</b> We sought approval for new process for patients who can only take part in the study through use of their routine clinical scan (not research scan). Included sending the Aphasia Recovery and Therapy Questionnaire (AR&TQ) before we potentially see them for a language assessment. This will apply to patients who have consented to the study at their recruiting site. We added the process to the Protocol.  We also made the following change on page 14: Capitalised 'Aphasia Recovery and Therapy Questionnaire' and added acronym.		Yes	
	PLORAS_Protocol_V4_February_2016	16/02/2016		
	1g__PLORAS_Clinical_Scan_On_Hold_Letter_V1_January_2016	21/01/2016		
	Notice_of_Amendment_6	16/02/2016		
	13-LO-1515_SA6_REC_Acknowledgement	17/02/2016		
	13-LO-1515_SA5_REC_Favourable_Opinion	16/03/2016		
7	<b>Summary:</b>		Yes	A

	<p>We sought approval for several changes. Some changes were made at the request of our external recruiting sites, to facilitate their recruitment procedures. Others were initiated internally by the PLORAS Research Team, partly again to facilitate smoother recruitment and testing procedures and, importantly for the welfare of our participants, to simplify and reduce what can be burdensome paperwork for participants with communication difficulties. We also made changes to our IRAS form to allow for the addition of external research sites in Wales and to reflect that part of the study would be undertaken as an educational project (by UCL MSc Speech and Language Sciences students).</p> <p>See supporting documents for all changes:</p> <ul style="list-style-type: none"> <li>• Covering Letter for Substantial Amendment 7</li> <li>• PLORAS Change Summary SA7</li> </ul>			
	1a__PLORAS_A5_Booklet_3.0_20171123	23/11/2017		
	1b__PLORAS_A4_Recruitment_Poster_3.0_20171123	23/11/2017		
	1d__PLORAS_Invitation_for_Study_Sites_PIC_Sites_5.0_20171212	12/12/2017		
	1d-P__PLORAS_Invitation_for_Study_Sites_PIC_Sites_3.0_20171212	12/12/2017		
	1h-P__PLORAS_Follow-Up_Invite_(NBoL)_1.0_20171212	12/12/2017		
	1i-P__PLORAS_Follow-Up_Invite_1.0_20171212	12/12/2017		
	2__PLORAS_Participant_Information_Sheet_4.0_20171212	12/12/2017		
	2-C__PLORAS_Consultee_Information_Sheet_4.0_20171212	12/12/2017		
	2-P__PLORAS_Participant_Information_Sheet_4.0_20171212	12/12/2017		
	2S__PLORAS_Participant_Information_Sheet_External+_4.0_20171212	12/12/2017		
	2S-C__PLORAS_Consultee_Information_Sheet_External+_4.0_20171212	12/12/2017		
	2S-P__PLORAS_Participant_Information_Sheet_External+_4.0_20171212	12/12/2017		
	3__PLORAS_Screening_Questionnaire_4.0_20171212	12/12/2017		
	3E__PLORAS_Screening_Questionnaire_External_4.0_20171212	12/12/2017		
	3E-P__PLORAS_Screening_Questionnaire_External_4.0_20180313	13/03/2018		
	3-P__PLORAS_Screening_Questionnaire_4.0_20180313	13/03/2018		
	3S__PLORAS_Screening_Questionnaire_External+_4.0_20171212	12/12/2017		
	3S-P__PLORAS_Screening_Questionnaire_External+_4.0_20171212	12/12/2017		
	4__PLORAS_Consent_Form_4.0_20171212	12/12/2017		
	4-C__PLORAS_Declaration_Form_4.0_20171212	12/12/2017		
	4E__PLORAS_Consent_Form_External_4.0_20171212	12/12/2017		

	4E-C_PLORAS_Declaration_Form_External_4.0_20171212	12/12/2017		
	4E-P_PLORAS_Consent_Form_External_4.0_20171212	12/12/2017		
	4-P_PLORAS_Consent_Form_4.0_20171212	12/12/2017		
	4S_PLORAS_Consent_Form_External+ 4.0_20171212	12/12/2017		
	4S-C_PLORAS_Declaration_Form_External+ 4.0_20171212	12/12/2017		
	4S-P_PLORAS_Consent_Form_External+ 4.0_20171212	12/12/2017		
	7a_PLORAS_Aphasia_Recovery_and_Therapy_Questionnaire_2.0_20171212	12/12/2017		
	7b_PLORAS_Carer_Aphasia_Recovery_and_Therapy_Questionnaire_1.0_20171212	12/12/2017		
	7c_PLORAS_Bilingual_Language_History_Questionnaire_1.0_20171212	12/12/2017		
	8a_PLORAS_Tattoo_Form_1.0_20171212	12/12/2017		
	8a-P_PLORAS_Tattoo_Form_1.0_20171212	12/12/2017		
	PLORAS_Protocol_5.0_20171212	12/12/2017		
	Notice_of_Amendment_7	12/12/2017		
	Covering_Letter_for_Substantial_Amendment_7	25/01/2018		
	PLORAS_Change_Summary_SA7	19/03/2018		
	13-LO-1515_SA7_REC_Validation	23/02/2018		
	13-LO-1515_SA7_REC_Favourable_Opinion	15/03/2018		
	13-LO-1515_SA7_HRA_Approval	15/03/2018		
8	<b>Summary:</b> We sought approval to increase the planned number of participants recruited to the study. This involved making changes to A59 and A60 on the IRAS form only.  No new documents were created and no changes to the PLORAS protocol were made (as the sample size had not been specified in the protocol).		Yes	A
	Notice_of_Amendment_8	25/07/2018		
	13-LO-1515_SA8_REC_Validation	25/07/2018		
	13-LO-1515_SA8_REC_Favourable_Opinion	15/08/2018		
9	<b>Summary:</b>  We sought approval for several changes. These were initiated internally by the PLORAS Research Team.		Yes	A

	<p>Changes made:</p> <ul style="list-style-type: none"> <li>• Clarifying the way we will use and store participant data. We added a privacy notice to all participant information sheets that is in line with the General Data Protection Regulation (2018). This replaces the temporary HRA information sheet we were using since the regulation came into effect.</li> <li>• Reflecting changes in the study. PLORAS will be using new methods to collect research data from participants (via online questionnaires) at an earlier stage in their participation (in order to facilitate faster data collection). These questionnaires will be administered by us (not external sites) and will ask participants about their speech and language recovery, therapy received, and other questions related to demographic information. These are separate to the information provided on the initial screening questionnaires completed at our external research sites. There was no change to external site activities as a result of this.</li> <li>• Reflecting patient and public involvement activities we plan to carry out (such as participant focus groups). We created new participant information and consent documents for these activities. There was no change to external site activities as a result of this.</li> <li>• Facilitating recruitment procedures for our external recruiting sites. All of our recruitment documents were updated as part of this amendment.</li> <li>• We also made changes to our IRAS form to ensure consistency with our updated study protocol.</li> </ul> <p>See supporting documents for all changes:</p> <ul style="list-style-type: none"> <li>• Covering Letter for Substantial Amendment 9</li> <li>• PLORAS Change Summary SA9</li> </ul>			
	2__PLORAS_Participant_Information_Sheet_5.0_20200501	01/05/2020		
	2-C__PLORAS_Consultee_Information_Sheet_5.0_20200501	01/05/2020		
	2D__PLORAS_Discussion_Groups_Information_Sheet_1.0_20200514	14/05/2020		
	2D-P__PLORAS_Discussion_Groups_Information_Sheet_1.0_20200514	14/05/2020		
	2G__PLORAS_GP_Information_Sheet_3.0_20200501	01/05/2020		
	2OD-P__PLORAS_Online_Discussion_Groups_Information_Sheet_1.0_20200514	14/05/2020		
	2-P__PLORAS_Participant_Information_Sheet_5.0_20200501	01/05/2020		

	2S_PLORAS_Participant_Information_Sheet_External+_5.0_20200501	01/05/2020		
	2S-C_PLORAS_Consultee_Information_Sheet_External+_5.0_20200501	01/05/2020		
	2S-P_PLORAS_Participant_Information_Sheet_External+_5.0_20200501	01/05/2020		
	3_PLORAS_Screening_Questionnaire_5.0_20200501	01/05/2020		
	3E_PLORAS_Screening_Questionnaire_External_5.0_20200501	01/05/2020		
	3E-P_PLORAS_Screening_Questionnaire_External_5.0_20200501	01/05/2020		
	3-P_PLORAS_Screening_Questionnaire_5.0_20200501	01/05/2020		
	3S_PLORAS_Screening_Questionnaire_External+_5.0_20200501	01/05/2020		
	3S-P_PLORAS_Screening_Questionnaire_External+_5.0_20200501	01/05/2020		
	4_PLORAS_Consent_Form_5.0_20200501	01/05/2020		
	4-C_PLORAS_Declaration_Form_5.0_20200501	01/05/2020		
	4D_PLORAS_Discussion_Groups_Consent_Form_1.0_20200514	14/05/2020		
	4E_PLORAS_Consent_Form_External_5.0_20200501	01/05/2020		
	4E-C_PLORAS_Declaration_Form_External_5.0_20200501	01/05/2020		
	4E-P_PLORAS_Consent_Form_External_5.0_20200501	01/05/2020		
	4OD-P_PLORAS_Online_Discussion_Groups_Consent_Form_1.0_20200514	14/05/2020		
	4-P_PLORAS_Consent_Form_5.0_20200501	01/05/2020		
	4S_PLORAS_Consent_Form_External+_5.0_20200501	01/05/2020		
	4S-C_PLORAS_Declaration_Form_External+_5.0_20200501	01/05/2020		
	4S-P_PLORAS_Consent_Form_External+_5.0_20200501	01/05/2020		
	7a_PLORAS_Aphasia_Recovery_and_Therapy_Questionnaire_3.0_20200501	01/05/2020		
	7b_PLORAS_Carer_Aphasia_Recovery_and_Therapy_Questionnaire_2.0_20200501	01/05/2020		
	PLORAS_Protocol_6.0_20200514	14/05/2020		
	20200514_13-LO-1515_SA9_REC_Form	14/05/2020		
	Notice_of_Amendment_9	14/05/2020		
	Covering_Letter_for_Substantial_Amendment_9	14/05/2020		
	PLORAS_Change_Summary_SA9	24/06/2020		
	20200610_13-LO-1515_SA9_REC_Validation	10/06/2020		
	20200624_13-LO-1515_SA9_REC_Favourable_Opinion	24/06/2020		
	20200625_13-LO-1515_SA9_HRA_Approval	25/06/2020		

10	<p><b>Summary:</b></p> <p>Changes were made to: i) improve the accessibility of study information (with specific regard to our stroke patient population), ii) increase the recruitment end date to 31st August 2027 (following a successful funding outcome), iii) amend the study inclusion criteria (to increase focus on stroke patients who have/had communication difficulties), and iv) to update participant and study site procedures following the COVID-19 pandemic. Specifically, all study sites are now required to provide copies of participant routine CT/MRI scans to PLORAS. This should not have a significant impact on our study sites as they have been asked to provide this data previously. Participants are no longer required to visit our research centre in London to take part and can complete all measures and assessments from the comfort of their own homes. Some additional measures have been developed which ask participants for further information about their speech and language recovery.</p> <p>The research design and methodology has not been significantly changed, nor has the scientific value of the study.</p> <p>As part of this amendment, changes were made to the PLORAS protocol, IRAS form and supporting documentation to reflect the above. In addition minor changes were made to: i) add details of new research staff members, ii) update PI details at study sites and iii) to add/remove study sites.</p>		Yes	A
	133939-PLORAS-protocol-7.0-13.10.2022	13/10/2022		
	133939-PLORAS-participating-study-sites-2.0-13.10.2022	13/10/2022		
	133939-PLORAS-IRAS-form-full-data-set-13.10.2022	13/10/2022		
	133939-1d-PLORAS-invitation-for-study-sites-6.0-13.10.2022	13/10/2022		
	133939-2-PLORAS-participant-information-booklet-6.0-13.10.2022	13/10/2022		
	133939-2a-PLORAS-privacy-notice-2.0-13.10.2022	13/10/2022		
	133939-2C-PLORAS-consultee-information-sheet-6.0-13.10.2022	13/10/2022		
	133939-3-PLORAS-participant-consent-form-6.0-13.10.2022	13/10/2022		
	133939-3C-PLORAS-consultee-declaration-form-6.0-13.10.2022	13/10/2022		
	133939-4-PLORAS-participant-entry-form-for-study-sites-6.0-16.11.2022	16/11/2022		
	133939-4P-PLORAS-participant-entry-form-6.0-16.11.2022	16/11/2022		
	133939-PLORAS-about-you-questionnaire-1.0-13.10.2022	13/10/2022		



	133939-SA10-PLORAS-amendment-tool-31.10.2022	31/10/2022		
	133939-SA10-PLORAS-wellcome-funding-award-letter-18.02.2022	18/02/2022		
	133939-SA10-sponsor-approval-email-01.11.2022	01/11/2022		
	133939-SA10-REC-favourable-opinion-email-12.12.2022	12/12/2022		
	133939-SA10-REC-favourable-opinion-letter-12.12.2022	12/12/2022		
	133939-SA10-HRA-approval-email-19.12.2022	19/12/2022		
11	<p>Changes were made to the Participant Consent Form (document 3) to improve accessibility and to separate the form into two parts. This is to account for inclusion of participants who may require greater communication support during the informed consent conversation.</p> <p>An Interaction Aid is also being introduced. This is a resource for CRN staff to use with participants to support the informed consent conversation.</p> <p>Minor changes were also made to:</p> <ul style="list-style-type: none"> <li>• Consultee Declaration Form (document 3C) for consistency with the Participant Consent Form (wording changes)</li> <li>• Participant Summary Sheet (document 2P) for consistency with the Interaction Aid (mainly changes to formatting)</li> <li>• Invitation to Study letter (1d) to improve accessibility (mainly changes to formatting).</li> <li>• 'About You' questionnaire (only used by the PLORAS Research Team) to add further questions.</li> <li>• Study Protocol - based on feedback from our participating sites, we have added more detail to the Inclusion criteria and Methods sections of the protocol for clarity. Appendix 2 (document version control) was also updated. See appendix 3 in the new protocol and the attached amendment tool for a list of all minor changes made.</li> </ul>		Yes	A
	133939_SA11_PLORAS_Amendment_Tool_21.08.2023	21/08/2023		
	133939-PLORAS-protocol-9.0-21.08.2023	21/08/2023		
	133939-1d-PLORAS-invitation-for-study-sites-8.0-21.08.2023	21/08/2023		
	133939-2P-PLORAS-participant-summary-sheet-2.0-21.08.2023	21/08/2023		

	133939-3-PLORAS-participant-consent-form-8.0-21.08.2023	21/08/2023		
	133939-3C-PLORAS-consultee-declaration-form-8.0-21.08.2023	21/08/2023		
	133939-PLORAS-Interaction-Aid-August-2023	21/08/2023		
	133939-PLORAS-about-you-questionnaire-1.1-21.08.2023	21/08/2023		