APPENDICIES

Appendix A

Consent Form

Title	A Double-Blind, Placebo Controlled, Randomised Phase II Trial of Probucol in Alzheimer's Disease (PIA-Study): The Impact on Cognition		
Protocol number	PIA-2020		
Project sponsor	Curtin University		
Principal investigator	Associate Professor Roger Clarnette		
Clinical contact person	Emily Corti	PHONE	
24-hour medical contact	Roger Clarnette	PHONE	EMAIL

Note: All parties signing the consent section must date their own signature.

Declaration by participant

- I have read, or have had read to me, and I understand the General Information PICF as well as this Participant Information Sheet and Consent Form.
- I have had the opportunity to have a member of my family or another person present while the study is explained to me.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
- I understand the purposes, procedures and risks of the research described in this Participant Information Sheet. Although I understand that the purpose of this study is to improve the quality of medical care, it has also been explained to me that my involvement may not be of any direct benefit to me.
- I understand that access may be required to my medical records for the purpose of this study as well as for quality assurance, auditing and in the event of a serious adverse event. I understand that such information will remain confidential.
- I understand that I will be randomised to either the Probucol (Lorelco™) or Placebo group, and that neither I nor the Study Doctor will know which group I am in.
- I understand and agree to my study partner providing information about my health to the Study Doctor.
- I consent to my local doctor being notified of my participation in this study and any clinically relevant information noted by the Study Doctor in the conduct of the study.
- I agree to adhere to the protocol requirements and restrictions as laid out in this Participant Information Sheet.
- I understand that I must use adequate contraception during the study. In the event of myself or my partner becoming pregnant, I must inform the Study Doctor immediately.
- I am 18 years of age and under 85 years of age.
- I understand that I will be given a signed copy of this document to keep.

Signature	_____	Date_____	Time_____
Name of participant (please print)	_____ First, Middle Name or Initial, Last (must be as per photo ID)		

Declaration by trial doctor

I have given a verbal explanation of the clinical trial, its procedures and risks and I believe that the participant has understood that explanation.

Signature	_____	Date_____	Time_____
Name of trial doctor (please print)	_____		

Appendix B

Consent Form for Continued Participation in the Event of Cognitive Decline

Title	A Double-Blind, Placebo Controlled, Randomised Phase II Trial of Probucol in Alzheimer's Disease (PIA-Study): The Impact on Cognition	
Protocol number	PIA-2020	
Study Phase	Phase 2	
Global Sponsor	Curtin University	
Study Doctor		
Site contact person	Emily Corti	PHONE
24-hour medical contact	Associate Prof Roger Clarnette PHONE	EMAIL

Note: All parties signing the consent section must date their own signature.

Declaration by Participant

- I have read, or have had read to me, and I understand the participant information and consent form.
- I have had the opportunity to have a member of my family or another person present while the study is explained to me.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
- I understand that the Study Doctor has the right to withdraw me from the study at any point.
- I understand that I will be given a signed copy of this document to keep.

I consent to continue my participation in the study in the event that my memory and thinking skills decline during the study.

Signature	_____	Date_____	Time_____
Name of participant (please print)	_____ First Name, Middle Name or Initial, Last Name		

Declaration by Study Doctor

I have given a verbal explanation of the study, its procedures and risks and I believe that the participant has understood that explanation.

Signature	_____	Date_____	Time_____
Name of Study Doctor (please print)	_____		

Appendix C

Consent Form for the Use and Storage of Blood Samples for Future Research

Title	A Double-Blind, Placebo Controlled, Randomised Phase II Trial of Probucol in Alzheimer's Disease (PIA-Study): The Impact on Cognition	
Protocol number	PIA-2020	
Study Phase	Phase 2	
Global Sponsor	Curtin University	
Study Doctor		
Site contact person	Emily Corti	0468 532 458
24-hour medical contact	Associate Prof Roger Clarnette 0415 956 611	Roger.Clarnette@health.wa.gov.au

Note: All parties signing the consent section must date their own signature.

Declaration by Participant

- I have read, or have had read to me, and I understand the participant information and consent form.
- I have had the opportunity to have a member of my family or another person present while the study is explained to me.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
- I understand the purposes, procedures and risks of the research described in this Participant Information Sheet. Although I understand that the purpose of this study is to improve the quality of medical care, it has also been explained to me that my involvement may not be of any direct benefit to me.
- I consent to my local doctor being notified of my participation in this study and any clinically relevant information noted by the Study Doctor in the conduct of the study.
- I agree to adhere to the protocol requirements and restrictions as laid out in the main Participant Information Sheet and this Participant Information Sheet.
- I understand that I must use adequate contraception during the study. In the event of myself or my partner becoming pregnant, I must inform the Study Doctor immediately.
- I am over 18 years of age, or younger than 85 years of age.
- I understand that I will be given a signed copy of this document to keep.

I consent to have additional blood samples taken for future research purposes in Alzheimer's Disease and for blood samples taken from this study to be stored and used for future research purposes. I also consent to being contacted in the future about providing additional blood samples for future Alzheimer's related projects

Signature	_____	Date_____	Time_____
Name of participant (please print)	_____ First Name, Middle Name or Initial, Last Name		

Declaration by Study Doctor

I have given a verbal explanation of the study, its procedures and risks and I believe that the participant has understood that explanation.

Signature	_____	Date_____	Time_____
Name of Study Doctor (please print)	_____		

Appendix D

Consent Form

Title	A Double-Blind, Placebo Controlled, Randomised Phase II Trial of Probucol in Alzheimer's Disease (PIA-Study): The Impact on Cognition		
Protocol number	PIA-2020		
Project sponsor	Curtin University		
Principal investigator	Associate Professor Roger Clarnette		
Clinical contact person	Emily Corti	PHONE	
24-hour medical contact	Roger Clarnette	PHONE	EMAIL

Note: All parties signing the consent section must date their own signature.

Declaration by study partner

- I have read, or have had read to me, and I understand the General Information PICF as well as this Partner Information Sheet and Consent Form.
- I agree to the above requirement of study partners, as set out in the Participant Information sheet and Consent form. I also acknowledge that at no time am I, as the study partner, receiving the treatment.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
- I freely agree to meet the minimum study requirements which includes; attending one screening visit, completing a questionnaire at the start, at 6 months, and at the end of the study, and be available by phone monthly, as needed.
- I understand that by consenting to the minimum study requirements, the study participant may continue through the screening phase of the study and, if eligible, will receive the study medication.
- I understand that I will be given a signed copy of this document to keep.

Signature	_____	Date_____	Time_____
Name of study partner (please print)	_____ First, Middle Name or Initial, Last (must be as per photo ID)		

Declaration by trial doctor

I have given a verbal explanation of the clinical trial, its procedures and risks and I believe that the study partner has understood that explanation.

Signature	_____	Date_____	Time_____
Name of trial doctor (please print)	_____		