UNIVERSITY OF CAMBRIDGE

Cambridge University Hospitals NHS
NHS Foundation Trust

INFORMED CONSENT FORM

Study Title: INvestigating the lowest Threshold of vascular bENefits from LDL cholesterol lowering with a PCSK9 mAb InhibiTor (alirocumab) in patients with stable cardiovascular disease (INTENSITY-HIGH)

Chief Investigator: Dr Joseph Cheriyan **Participant Number:** _____

If you agree with each sentence below, please initial the box		**INITIALS**
1	I have read and understood the Participant Information Sheet version ##, dated #### for the above study and I confirm that the study procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.	
3	I understand that sections of my medical notes or information related directly to my participation in this study may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	
4	I understand that my GP will be informed of my participation in this study and sent details of the INTENSITY-HIGH study.	
5	I have read and understood the compensation arrangements for this study as specified in the Participant Information Sheet.	
6	I understand that the doctors in charge of this study may close the study, or stop my participation in it at any time without my consent.	
7	I have read and understood my responsibilities for the study including using appropriate contraception as listed in section 6.	
8	I agree to provide blood and serum samples for research related to this study, which may be stored until the end of the study.	
9	I understand that I should notify any insurance providers (as listed in section 6 of the Patient Information Sheet) as failure to notify them could affect or invalidate my cover.	
10	I agree to participate in the INTENSITY-HIGH study.	

OPTIONAL		**YES**	**NO**
11	I give my permission to be re-contacted in the future by this research team and other research teams to invite me to take part in new studies that may be of interest. I understand that this does not oblige me to take part in further research.		
12	I give my permission to allow anonymised samples which have been donated by myself to be stored and used in other future ethically approved studies.		
13	I give my permission to take part in the optional INTENSITY-HIGH PET/MR sub-study if I meet the local guidelines for the PET/MR scan.		

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

Time of Consent (24hr clock) _____:_____

1 copy for the patient, 1 copy for the study team, 1 copy to be retained in the hospital notes.

Cacciottolo PJ, *et al. BMJ Open* 2021; 11:e037457. doi: 10.1136/bmjopen-2020-037457