>OMF 4.9.3

INTERVENTIONAL RESEARCH CHECKLIST



All of the following items must be made available to the St John Clinical Research Coordinator prior to commencing any clinical research involving patients, patient information, staff or the operational sites of St John. Documents can be made available via HDEC http://ethics.health.govt.nz/ application system by authorising St John to view your project file.

St John registration number RM:	
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Documentation	Comments	Date sent to St John
Project Registration	Once your registration form has been submitted to the St John Clinical research coordinator you will be given a registration (RM) number.	
Project Proposal	Email to <u>clindevhelp@stjohn.org.nz</u> Attn: Clinical Research Coordinator.	
Ethics Application Form	For HDEC: St John must be selected as an authoriser in the online HDEC system. For other Institutional Ethics Committees: the final approved version is required.	
Participant Information Sheet	Final St John version required.	
Participant consent form	Final St John version required.	
Participant advertisements/ letters of invitation (if any)	Final St John version required.	
Indemnity Agreement (signed)	For sponsored research.	
Clinical Trial Agreement (signed)	For sponsored research.	
Funding Contract (if any)	Required only if signed by St John.	
Evidence of cultural consultation	Required for all studies.	
St John Confidentiality Agreement	Required for any non-St John staff accessing St John patients, patient information or premises.	
Letter of Responsibility from Institution	Required where PI is a student researcher and is accessing St John patient information or premises.	
Ethics Committee Approval Letter	For HDEC: St John must be selected as an authoriser in the online HDEC system. For other Institutional Ethics Committees: the final approval letter is required.	
Written evidence of peer review	Required for all studies.	

Any queries should be emailed to <u>clindevhelp@stjohn.org.nz</u> Attn: Clinical Research Coordinator.

OPERATIONS MANUAL			
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Authorised by: Michael Brooke, Operations Director	Date for review:		