

Wednesday, 24 April 2019

Prof Maria Antoinette Fiatarone Singh
Exercise Health and Performance; Faculty of Health Sciences
Email: maria.fiataronesingh@sydney.edu.au

Dear Maria Antoinette,

Your request to modify this project, which was submitted on 25/03/2019, has been considered.

After consideration of your response to the comments raised the project has been approved to proceed with the proposed amendments.

Protocol Number: 2018/981
Protocol Title: COLONiC: Consequences of OLive Oil replacemenNt on ulcerative Colitis

Documents Approved:

Date Uploaded	Type	Document Name and Version No
21/03/2019	Telephone Scripts	COLONIC Telephone Screen 12.03.2019 CLEAN
21/03/2019	Questionnaires/Surveys	Food Choice Questionnaire
21/03/2019	Questionnaires/Surveys	Food Related Quality of Life Questionnaire
21/03/2019	Interview Questions	Weekly Status Check 12.03.2019 CLEAN
21/03/2019	Participant Info Statement	PIS for UC participants v2.2 14.03.2019 CLEAN
25/03/2019	Questionnaires/Surveys	Demographic Q 12.03.2019 CLEAN
16/04/2019	Study Protocol	COLONIC Protocol V2.1

Special Conditions of Approval for Clinical Trials

- **This letter constitutes ethical approval only.** This project cannot proceed at any site until the necessary research governance authorisation is obtained. If your study is sponsored by the University or is to be conducted on a University of Sydney site you may need to comply with additional University governance requirements prior to commencing. Please contact the Clinical Trials Governance Office at clinical-trials.research@sydney.edu.au
- Clinical Trials must be registered on a clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). For trials conducted in Australia or New Zealand registration should be on the Australian New Zealand Clinical Trial Registry before recruitment of the first subject (<http://www.anzctr.org.au/>).

Please contact the Ethics Office should you require further information or clarification.



Sincerely,

Associate Professor Mark Arnold
Chair
Modification Review Committee Chair (MRC 2)

cc. Clinical Trial Governance

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) [National Statement on Ethical Conduct in Human Research \(2007\)](#) and the NHMRC's [Australian Code for the Responsible Conduct of Research \(2007\)](#).