Friday, 24 May 2019

Prof David Hunter
Northern Clinical School: Kolling Institute; Faculty of Medicine and Health
Email: david.hunter@sydney.edu.au

Dear David,

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

I am pleased to inform you that after consideration of your response, your project has been approved.

Details of the approval are as follows:

Project No.:	**2018/766**
Project Title:	**Internet Based Randomized Controlled Trial of a Supplement Combination in Hand Osteoarthritis (RADIANT study)**
Authorised Personnel:	**Hunter David; Deveza Leticia; Eyles Jillian; Fedorova Tatyana; Liu Xiaoqian; Robbins (nee: Ferreira De Meneses) Sarah Rubia; Virk Sonika; McLachlan Andrew;**
Approval Period:	**24/05/2019** to **24/05/2023**
First Annual Report Due:	**24/05/2020**

Documents Approved:

Date Uploaded	Type	Document Name/Version
23/05/2019	Participant Info Statement	PISCF_v5_21 May 2019
07/05/2019	Study Protocol	Protocol_v5_07 May 2019
07/05/2019	Other Type	List of excluded health conditions_v1_02 May 2019
07/05/2019	Other Type	Participant Identification Card_v2_30 Apr 2019
07/05/2019	Other Type	Investigator's Brochure_v4_03 May 2019
07/05/2019	Advertisements/Flyer	Social media advertisement template_v1_30 Apr 2019
07/05/2019	Questionnaires/Surveys	eCRFs_v4_07/052019
07/05/2019	Telephone Scripts	Consent Checklist_v1_02 May 2019
07/05/2019	Advertisements/Flyer	IBJR website advertisement_v1_02 May 2019
07/05/2019	Recruitment Letter/Email	Invitation email template_v1_02 May 2019
07/05/2019	Other Type	Monitoring plan_v1_02 May 2019
07/05/2019	Other Type	Participant Information Booklet_v3_02 May 2019
07/05/2019	Other Type	Participant instructions_v1_06 May 2019
07/05/2019	Advertisements/Flyer	poster_flyer_v1_12 Mar 2019

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/).

- A trial to be conducted under the Clinical Trials Notification (CTN) scheme should not commence until it has been notified to the Therapeutic Goods Administration (TGA). If your study is sponsored by the University, please contact Clinical Trials Governance to arrange submission of your CTN.

THE UNIVERSITY OF SYDNEY

Condition/s of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
  - ➢ Serious or unexpected adverse events (which should be reported within 72 hours).
  - ➢ Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.
- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.
- The Ethics Office may conduct audits on approved projects.
- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

This letter constitutes ethical approval only.

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

Sincerely,

Glen Davis
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Professor Glen Davis
Chair
Human Research Ethics Committee (HREC 2)

cc. Clinical Trial Governance

The University of Sydney 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)