Ethics Approval Letter

28/09/2021

To: Professor Flanagan

Project ID: 26241

Project Title: COVID-19 Vaccination of Vulnerable Populations (COVULPOP)

The above named project has been approved by the University of Tasmania Human Research Ethics Committee on 28 September 2021.

Approval has been granted for the following documentation:

Submission Document Name	Submission Document File Name	Submission Document Type	Submission Document Date	Submission Document Version
COVULPOP_Human Ethics_Privacy Form_04Aug2021	COVULPOP_Human Ethics_Privacy Form_04Aug2021.docx	Other Documents	04/08/2021	1
COVULPOP_Pamphlet_01Aug21	COVULPOP_Pamphlet_01Aug21.pdf	ADVERTISING MATERIAL	01/08/2021	1
COVULPOP_Poster_01Aug21	COVULPOP_Poster_01Aug21.pdf	ADVERTISING MATERIAL	01/08/2021	1
Launceston Medical Centre Collaboration letter draft 06July2021	Launceston Medical Centre Collaboration letter draft 06July2021.docx	LETTER OF SUPPORT	06/07/2021	1
COVULPOP_InformationSheet_Version 1_01Aug21	COVULPOP_InformationSheet_Version 1_01Aug21.pdf	PARTICIPANT INFORMATION AND CONSENT FORM	01/08/2021	1
COVULPOP_Consent_Version1_01Aug21	COVULPOP_Consent_Version1_01Aug21.pdf	PARTICIPANT INFORMATION AND CONSENT FORM	01/08/2021	1
CardioMedSurveyTool	CardioMedSurveyTool.pdf	QUESTIONNAIRE	20/08/2021	1
DepressionAnxietyStressScale (DASS-21)	DepressionAnxietyStressScale (DASS-21).pdf	QUESTIONNAIRE	01/08/2021	1
EdinburghPostnatalDepressionScale	EdinburghPostnatalDepressionScale.pdf	QUESTIONNAIRE	20/08/2021	1
COVULPOP_InformationSheet_Version 2_23Sep21_clean	COVULPOP_InformationSheet_Version 2_23Sep21_clean.pdf	PARTICIPANT INFORMATION AND CONSENT FORM	23/09/2021	2
COVULPOP_InformationSheet_Version 2_23Sep21_tracked	COVULPOP_InformationSheet_Version 2_23Sep21_tracked.pdf	PARTICIPANT INFORMATION AND CONSENT FORM	23/09/2021	2
COVULPOP Poster V2 20Sep21	COVULPOP Poster V2 20Sep21.pdf	ADVERTISING MATERIAL	20/09/2021	2
COVULPOP Poster V2 20Sep21_tracked	COVULPOP Poster V2 20Sep21_tracked.pdf	ADVERTISING MATERIAL	20/09/2021	2
COVULPOP Pamphlet V2 20Sep21	COVULPOP Pamphlet V2 20Sep21.pdf	ADVERTISING MATERIAL	20/09/2021	2
COVULPOP Pamphlet V2 20Sep21_tracked	COVULPOP Pamphlet V2 20Sep21_tracked.pdf	ADVERTISING MATERIAL	20/09/2021	2
COVULPOP_Protocol_Version2_23Sep21_tracked	COVULPOP_Protocol_Version2_23Sep21_tracked.pdf	PROTOCOL (TRACKED)	23/09/2021	2
COVULPOP_Protocol_Version2_23Sep21_clean	COVULPOP_Protocol_Version2_23Sep21_clean.pdf	PROTOCOL	23/09/2021	2
COVULPOP Response to ethics questions 23Sep21	COVULPOP Response to ethics questions 23Sep21.docx	OTHER PROJECT-RELATED DOCUMENTATION	23/09/2021	1

The University of Tasmania Human Research Ethics Committee has provided approval for the project to be conducted at the following sites:

- Prof Flanagan Lab, School of Health Sciences, Invermay, Tasmania, Australia
- Launceston General Hospital (LGH)
- School of Health and Biomedical Sciences , RMIT University, Bundoora, Melbourne, Victoria 3083, Australia
- Launceston Medical Centre, 247 Wellington Street, Launceston, Tasmania 7250, Australia
- Dr Amanda Dennis's Private Rooms, Lyttleton Street, Launceston, Tasmania, Australia
- WHO Collaborating Centre for Reference and Research on Influenza, The Peter Doherty Institute for Infection and Immunity, The University of Melbourne at the Peter Doherty Institute for Infection and Immunity Melbourne, Victoria 3000, Australia
- Human T cell Laboratory Head, Department of Microbiology and Immunology, The University of Melbourne at the Peter Doherty Institute for Infection and Immunity, Melbourne, Victoria 3000, Australia
- Centre of Innate Immunity and Infectious Diseases, The Hudson Institute of Medical Research, Monash University, Clayton Campus, Melbourne, Victoria 3168, Australia
- Wellcome Sanger Institute, Wellcome Genome Campus, Hinxton, UK
- Blizard Institute and Barts and The William Harvey Research Institute, The London Medical School, Queen Mary University of London, 4 Newark Street, London E1 2AT, UK

Please ensure that all investigators involved with this project have cited the approved versions of the documents listed within this letter and use only these versions in conducting this research project.

This approval constitutes ethical clearance by the University of Tasmania Human Research Ethics Committee. The decision and authority to commence the associated research may be dependent on factors beyond the remit of the ethics review process. For example, your research may need ethics clearance from other organisations or review by your research governance coordinator or Head of Department. It is your responsibility to find out if the approvals of other bodies or authorities are required. It is recommended that the proposed research should not commence until you have satisfied these requirements.

In accordance with the National Statement on Ethical Conduct in Human Research, it is the responsibility of institutions and researchers to be aware of both general and specific legal requirements, wherever relevant. If researchers are uncertain they should seek legal advice to confirm that their proposed research is in compliant with the relevant laws. University of Tasmania researchers may seek legal advice from Legal Services at the University.

The University of Tasmania Human Research Ethics Committee (HREC) operates under and is required to comply with the National Statement on the Ethical Conduct in Human Research.

Therefore, the Chief Investigator's responsibility is to ensure that:

(1) All investigators are aware of the terms of approval, and that the research is conducted in compliance with the HREC approved protocol or project description.

(2) Modifications to the protocol do not proceed until **approval** is obtained in writing from the HREC. This includes, but is not limited to, amendments that:

(i) are proposed or undertaken in order to eliminate immediate risks to participants;
(ii) may increase the risks to participants;
(iii) significantly affect the conduct of the research; or
(iv) involve changes to investigator involvement with the project.

Please note that all requests for changes to approved documents must include a version number and date when submitted for review by the HREC.

(3) Reports are provided to the HREC on the progress of the research and any safety reports or monitoring requirements as indicated in NHMRC guidance.

Guidance for the appropriate forms for reporting such events in relation to clinical and non-clinical trials and innovations can be located under the ERM "Help Tab" in "Templates". All adverse events must be reported regardless of whether or not the event, in your opinion, is a direct effect of the therapeutic goods being tested.

(4) The HREC is informed as soon as possible of any new safety information, from other published or unpublished research, that may have an impact on the continued ethical acceptability of the research or that may indicate the need for modification of the project.

(5) All research participants must be provided with the current Participant Information Sheet and Consent Form, unless otherwise approved by the Committee.

(6) This study has approval for four years contingent upon annual review. A Progress Report is to be provided on the anniversary date of your approval. Your first report is due on the anniversary of your approval**,** and you will be sent a courtesy reminder closer to this due date. Ethical approval for this project will lapse if a Progress Report is not submitted in the time frame provided.

(7) A Final Report and a copy of the published material, either in full or abstract, must be provided at the end of the project.

(8) The HREC is advised of any complaints received or ethical issues that arise during the course of the project.
(9) The HREC is advised promptly of the emergence of circumstances where a court, law enforcement agency or regulator seeks to compel the release of findings or results. Researchers must develop a strategy for addressing this and seek advice from the HREC.

Kind regards,

Ethics Executive Officer

UNIVERSITY of TASMANIA