

Monash University Human Research Ethics Committee

Approval Certificate

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

Project Number: 8031
Project Title: The Gut-Brain Axis in Huntington's Disease
Chief Investigator: Dr Yifat Glikmann-Johnston
Expiry Date: 27/06/2022

Terms of approval - failure to comply with the terms below is in breach of your approval and the *Australian Code for the Responsible Conduct of Research*.

1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, before any data collection can occur at the specified organisation.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash letterhead and the Monash University complaints clause must include your project number.
6. Amendments to approved projects including changes to personnel must not commence without written approval from MUHREC.
7. Annual Report - continued approval of this project is dependent on the submission of an Annual Report.
8. Final Report - should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected completion date.
9. Monitoring - project may be subject to an audit or any other form of monitoring by MUHREC at any time.
10. Retention and storage of data - The Chief Investigator is responsible for the storage and retention of the original data pertaining to the project for a minimum period of five years.

Thank you for your assistance.

Professor Nip Thomson

Chair, MUHREC

CC: Professor Julie Stout, Mr Cory Wasser

List of approved documents:

Document Type	File Name	Date	Version
Clinical Trial Detail Form	Clinical Trial Form	01/05/2017	1
Psychological inventories	CES-D-Stanford-Version	01/05/2017	1
Consent Form	Consent Form GBA Study	06/06/2017	1
Questionnaires / Surveys	Demographic Questionnaire	06/06/2017	1
Clinical Trial Agreement	CT56_Research Agreement_200417 (2)	06/06/2017	1
Supporting Documentation	Demographic Questionnaire	06/06/2017	1
Supporting Documentation	GBA Flyer	06/06/2017	1
Supporting Documentation	GBA Food Diary	06/06/2017	1
Explanatory Statement	Explanatory Statement Control 2017	06/06/2017	1
Explanatory Statement	Explanatory Statement HD 2017	06/06/2017	1