

13-Nov-18

**Professor Adam Guastella**  
**Brain and Mind Centre**  
**100 Mallett Street**  
**Camperdown NSW 2050**

**Dear Professor Guastella**

**Re: Application No:** 2018-05-322-A-1

**Study Title:** AXL-1224-2004-001: A Two-Arm, Single Sequence, Multiple Ascending Dose Study of the Safety and Tolerability of AB-1224 and AB-2004 in Young Adult & Pediatric Autism Spectrum Disorder Populations

**Type of Application:** Amendment/Investigator Brochure Form

**Name of the Documents Submitted and Approved:**

**Attachments**

AXL-001\_CGI-I Questionnaire\_Version 1 dated 16Oct2018  
AB-1224 Drug Instructions\_V.1 dated 17Oct2018\_Final  
AB-2004 Drug Instructions\_V.1.1 dated 31Oct2018\_Final  
AXL-001\_Stool\_Urine\_Home Collection\_Participant facing\_V3\_\_FINAL\_15Oct18  
Cohort 1 Participant Instructions - V1\_Screening\_30.11.18\_Final  
Cohort 1 Participant Instructions - V2\_Treatment 1\_30.11.18\_Final  
Cohort 1 Participant Instructions - V3\_Treatment 2\_30.11.18  
Cohort 1 Participant Instructions - V4\_Treatment 3\_30.11.18  
Cohort 2 Participant Instructions - V1\_Screening\_30.11.18\_Final  
Cohort 2 Participant Instructions - V2\_Treatment 1\_30.11.18\_Final  
Cohort 2 Participant Instructions - V3\_Treatment 2\_30.11.18\_Final  
Cohort 2 Participant Instructions - V4\_Treatment 3\_30.11.18\_Final  
Cohort 3-4 Participant Instructions - V1\_Screening\_30.11.18\_Final  
Cohort 3-4 Participant Instructions - V2\_Treatment 1\_30.11.18\_Final  
Cohort 3-4 Participant Instructions - V3\_Treatment 2\_30.11.18\_Final  
Cohort 3-4 Participant Instructions - V4\_Treatment 3\_30.11.18\_Final  
e-Diary\_Axial Dedo.Ai Aces Health\_ 8Oct2018  
e-Diary\_Axial Project 0001 Dedo.Ai-flows  
AXL-001\_CGI-S Questionnaire\_Version 1 dated 16Oct2018

Includes:

It is noted that, as per approval letter dated 5 November 2018, this application has received approval which is conditional upon receipt of the fully executed Standard Indemnity. The study must not commence until this document has been provided. Please submit the fully executed Standard Indemnity on an amendment form when available.

**Date of Approval:** 12-Nov-18

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics committee (HREC) has scientifically and ethically reviewed this study.

This Bellberry HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates as at May 2015) (National Statement).

I wish to advise that the Bellberry Human Research Ethics Committee has ethically approved these documents/changes.

**Details of Ethics Committee:**

It is the process of the Bellberry Human Research Ethics Committee not to disclose personal details of its reviewing members. This Project was considered by a Committee that fulfilled the requirements of the National Statement (2007) section 5.1.29-30. Please note that the Principal Investigator and Co-Investigators are not members of the Bellberry Human Research Ethics Committees and were not involved in the review of this study.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely

*Michael James*

**Michael James**

**Chair, Committee C (TGA HREC Code EC00430)**

**BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE**