

ETHICS COMMITTEE / IRB APPROVAL LETTER

From: Sydney Local Health District HREC
To: Dr. David O'Connor
Reference Number: SLHD-HREC-2024-0156-AMD-001
Date: 2024-11-20
Protocol: NVX-1218.22 -- NovaPlex-450 in Advanced NSCLC
Amendment: Protocol Amendment v2.1

Amendment Approval

Dear Dr. David O'Connor,

The Sydney Local Health District HREC has reviewed and approved Protocol Amendment v2.1 dated 2024-11-01 for the above-referenced study. The amendment includes:

- 1. Revised inclusion/exclusion criteria (Section 4.2)
- 2. Updated Informed Consent Form (ICF v2.1) -- all active subjects must be re-consented
- 3. Modified visit schedule -- Week 12 visit extended from Day 84 +/-3 to Day 84 +/-7

IMPORTANT: All currently enrolled subjects must provide updated consent using ICF v2.1 prior to their next scheduled study visit. Please ensure all site staff are trained on the protocol changes before implementing.

Approval Details

Status: APPROVED
Approval Date: 2024-11-20
Expiry Date: 2025-11-20
Renewal Required: Yes -- submit renewal 60 days before expiry

Chairperson Signature:

IRB Chairperson