

ETHICS COMMITTEE / IRB APPROVAL LETTER

From: New England IRB (NEIRB)
To: Dr. Emily Chen
Reference Number: NEIRB-2024-0112
Date: 2024-01-15
Protocol: NVX-1218.22 -- NovaPlex-450 in Advanced NSCLC
Amendment: N/A -- Initial Approval

Initial Approval

Dear Dr. Emily Chen,

The New England IRB (NEIRB) is pleased to confirm approval of the above-referenced clinical study at your institution. This approval is effective from 2024-01-15 and is valid for 12 months.

This approval covers:

- Protocol Version 1.0 (dated 2023-12-01)
- Informed Consent Form Version 1.0 (dated 2023-12-01)
- Patient recruitment materials as submitted

Conditions of approval:

1. Any protocol amendments must be submitted for review prior to implementation
2. Annual progress reports must be submitted
3. All serious adverse events must be reported within 7 days
4. The study must be conducted in accordance with ICH GCP E6(R2) guidelines

Approval Details

Status: APPROVED
Approval Date: 2024-01-15
Expiry Date: 2025-01-14
Renewal Required: Yes -- submit renewal 60 days before expiry

Chairperson Signature:

IRB Chairperson