Schedule 6

Special Conditions

**It is agreed that:**

1. the word ‘will’ be replaced with ‘must’ in the following parts of this Agreement:
* Paragraph C, Purpose of the Agreement
* Clauses 4.6, 4.7
* First sentence in clause 4.8
* Clause 4.10
* First sentence in clause 4.12
* Clauses 5.2 - 5.8 inclusive
* Clause 6.1, 6.6, 6.8,
* First sentence in 7.1
* Clauses 7.5, 7.6
* First sentence in clause 10.2
* First sentence in clause 10.3
* Clauses 13.7, 13.10
1. the definition of ‘Anti-Corruption Laws’ under clause 1.1 be replaced with the following:

**“Anti-Corruption Laws** includes the *Crimes Act 1961*, the *Secret Commissions Act 1910*, the *Anti-Money Laundering and Countering Financing of Terrorism Act 2009* or their replacements and other anti-corruption laws.”

1. the definition of ‘Multi-centre Study’ under clause 1.1 be replaced with the following:

**“Multi-centre Study** is a Study conducted by several investigators according to a single protocol at more than one Study Site.”

1. the definition of ‘Regulatory Authority’ under clause 1.1 be replaced with the following:

**“Regulatory Authority** means any body or person with lawful authority over the conduct of the Study at the Study Site and includes Medsafe and any overseas Regulatory Authorities that may require to audit, or require auditing of, any part of the Study or Study Materials.”

1. under clause 2.3, the second to last sentence is amended to read as follows:

“Protocol amendments that the Parties agree will not affect Study conduct payments as listed in **Schedule 2** and will not require an amendment of this Agreement.”

1. under clause 2.4, the first sentence is amended to read as follows:

## “The Parties agree as follows:”

1. under clause 2.4(1), ‘third Parties’ is amended to read as ‘third parties’
2. the word ‘and’ is inserted between clauses 3.3(15) and 3.3(16)
3. clause 5.9 is replaced with the following:

## “The CRO or Organisation must provide indemnity to the Institution against claims arising from the Study on the terms and conditions set out in the relevant form of an Indemnity and Compensation Agreement for Clinical Trials as set out in **Schedule 3**.”

1. clause 5.10 is replaced with the following:

## “The CRO or Organisation must comply with the NEAC *Ethical Guidelines for Intervention Studies* and must ensure that compensation is provided to Study Participants who are excluded from cover by section 32(6), or its equivalent replacement, of the *Accident Compensation Act 2001*, to at least an equivalent level to compensation under that Act as if the Study were not excluded from cover, as specified in the relevant form of an Indemnity and Compensation Agreement for Clinical Trials as set out in **Schedule 3**.”

1. clause 5.11 is replaced with the following:

## “The CRO and/or the Organisation must maintain appropriate insurance cover with respect to its activities and to meet its compensation and indemnity obligations under this Agreement in accordance with **Schedule 4** and **clauses** **5.9 and** **5.10.** This insurance is to be evidenced by a certificate of currency of insurance, as requested by the Institution from time to time.”

1. clause 6.4 is replaced with the following:

## “Save for its obligations under **clauses 5.9 and 5.10** which remain unaffected, the CRO reserves the right to refuse to pay to the Institution payments specific to Study Participants entered into the Study who do not meet the entry criteria specified in the Protocol or Study Participant visits that have not been conducted in accordance with the Protocol.”

1. clause 6.5 is replaced with the following:

## “Save for the CRO’s and the Organisation’s obligations under **clauses 5.9 and 5.10** which remain unaffected, if a Study Participant discontinues their participation in the Study or if the Study is terminated as a whole, only those costs incurred, or irrevocably committed, up until the date of discontinuation or termination, including costs of final visit and completion of all Case Report Forms, must be paid.”

1. clause 6.11 is replaced with the following:

## “The Parties agree that the compensation being paid under this section 6 is fair market value for the services being provided, and that no payments are being provided for the purpose of inducing anyone to purchase or prescribe any drugs, devices or products.  In addition, the Study Site shall not bill any Study Participant, patient, insurer, or governmental agency for any items, visits, services or expenses provided or paid for by, or on behalf of the CRO or the Organisation. Payments shall be made from funds provided by the Organisation and facilitated by the CRO.”

1. clause 7.3 is replaced with the following:

## “The Equipment and Software are provided at the risk of the CRO, but the Institution must take reasonable care in the use and secure storage of the same and the Institution is responsible for damage caused to or by the Equipment by the negligence of its Personnel while in the Institution's possession or control.”

1. clause 8.2 is replaced with the following:

## “The CRO must ensure that the Principal Investigator is supplied with such quantities of the Investigational Product as will be required for the purpose of the Study. The CRO must ensure that all supplied Investigational Product will be packaged in safe and appropriately labelled containers. The Organisation will at all times remain the owner of the Investigational Product.”

1. clause 13.1 is replaced with the following:

## “This Agreement commences from the date this Agreement is last signed by either the CRO or Institution. In the ordinary course of events this Agreement terminates when the CRO has made its final payment to the Institution and the Institution has received written Notification of Site closure and completion of the Institution’s ongoing responsibilities.”

1. clause 14.1 is replaced with the following:

## “No Party may commence legal proceedings against another in respect of a dispute arising in relation to this Agreement (except for urgent interlocutory relief and claims for compensation for injury to Study Participants under **clause 5.10)** unless the Parties have complied with this clause and that Party has first Notified the other Party in writing of the dispute and has used all reasonable endeavours to resolve the dispute with the other Party within 28 days of the giving of that Notice (**Initial Period**).”

1. the words ‘will be’ are replaced with ‘is’ in clause 15