

Insurance Risk Management Consulting

25<sup>th</sup> July 2018

# TO WHOM IT MAY CONCERN

We, the undersigned Insurance Brokers hereby certify that we have place the following Insurance:

# VERIFICATION OF INSURANCE

Unique Market Reference:	B1262FI0153318			
Туре:	Clinical Trials Insurance			
Insured:	University College London			
Period:	From: To:	01 <sup>st</sup> August 2018 31 <sup>st</sup> July 2019	Both days inclusive at Local Standard Time.	
Interest:	This Policy will indemnify/cover the Insured in respect of their Legal Liabilities arising out of the Insured's activities and as more fully disclosed within the Policy Wording.			
Limit of Indemnity:	As Attached			
Excess:	GBP 2,500 Each and Every Claim, including costs and expenses			
Underwriter:	100.0000	% Newline Syr	dicate 1218	

This document is for information only and does not make the person or organisation to whom it is issued an additional Insured, nor does it modify in any manner the Contract of Insurance between the Insured and the Insurers. Any amendment, change or extension to such Contract can only be affected by specific endorsement attached thereto.

Should the above mentioned Contract of Insurance be cancelled, assigned or changed during the above policy period in such manner as to affect this document, no obligation to inform the holder of this document is accepted by the undersigned or by the Insurers. The information provided is correct at the date of signature.

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Authorised Signatory Arthur J Gallagher



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Section	n	Limit of Liability		
1	Public Liability	GBP Not Insured		
		any one Occurrence (Legal Costs in addition)		
2	Products Liability/ Completed Operations	GBP applies to claims from Human Subjects resulting from the use of Investigational Entity in a Clinical Trial any one Claim and in aggregate (Legal Costs in addition)		
3	Legal Liability for Humar Clinical Trials	GBP 15,000,000 any one Claim and in aggregate (Legal Costs in addition)		
4 No Fault Compensation for Human Clinical Trials		or GBP 15,000,000 any one Claim and in aggregate (Legal Costs in addition)		
5	Errors and Omissions	GBP 15,000,000 any one <b>Claim</b> and in aggregate		
6	Medical Malpractice Liability	(Legal Costs inclusive)		
		GBP 10,000,000 any one <b>Claim</b> and in aggregate ( <b>Legal Costs</b> inclusive)		
Sections 2 to 6 and all Endorsements Combined		GBP 15,000,000 in aggregate ( <b>Legal Costs</b> in addition for Sections 2, 3 and 4 and <b>Legal Costs</b> inclusive for Sections 5 and 6)		
		The Limits of Liability are inclusive of the Deductible, interest and claimants' costs and expenses.		
Policy		Section 3 – Worldwide Section 4 - Worldwide excluding USA/Canada Section 5 - Worldwide Section 6 – Worldwide excluding USA/Canada		
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#### Definitions

Human Clinical Trial shall mean any investigational study conducted for the purposes of research and any research, data analysis, or other advice provided in relation to the study and its results

Medical Devices shall mean health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or an abnormal physical condition.

**Pharmaceutical** shall mean any placebo, or any substance taken by mouth, injected or inserted into an eye, a muscle, the skin, a blood vessel or a cavity of the body or applied to the skin to treat or prevent a disease, condition or symptom.



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#### SECTION 3 - LEGAL LIABILITY FOR HUMAN CLINICAL TRIALS

#### "CLAIMS MADE AND NOTIFIED" BASIS

#### COVER

The Underwriters shall, subject to the terms, conditions, Limits of Liability and exclusions of this Policy, indemnify the Insured against:

- (1) legal liability for damages in respect of any **Bodily Injury** to a **Research Subject**, provided that such liability is caused by an **Occurrence** within the **Policy Territory** and in connection with **Human Clinical Trials**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) Legal Costs in connection with paragraph (1) above,

provided that:

- (i) the Claim in respect of such liability is first made against the Insured during the Period of Insurance and is notified to the Underwriters in writing during the Period of Insurance; and
- (ii) all Bodily Injury resulting from or alleged to have resulted from the same Human Clinical Trial shall be considered as resulting from one Claim and having occurred during the period of insurance in which the first Claim is made against the Insured, irrespective of the number of claimants or the period over which Claims may thereafter be made against the Insured arising out of such Bodily Injury.

# SECTION 4 - NO FAULT COMPENSATION FOR HUMAN CLINICAL TRIALS

#### "CLAIMS MADE AND NOTIFIED" BASIS

#### COVER

The **Underwriters** shall, subject to the terms, conditions, **Limits of Liability** and exclusions of this **Policy**, indemnify the **Insured** against:

- liability to pay compensation and claimants' costs and expenses pursuant to the Conditions of Compensation in respect of Bodily Injury to a Research Subject;
- (2) Legal Costs in connection with paragraph (1) above,

provided that:

- (i) such liability is caused by an Occurrence within the Policy Territory and in connection with the Business and arises from the use of any Pharmaceutical or Medical Devices in Human Clinical Trials;
- the Insured has offered and the Research Subject has agreed to abide by the Conditions of Compensation set out below;
- (iii) the Claim in respect of such liability is first made against the Insured during the Period of Insurance and is notified to the Underwriters in writing during the Period of Insurance; and
- (iv) all Bodily Injury resulting from or alleged to have resulted from the same Human Clinical Trial shall be considered as resulting from one Claim and having occurred during the period of insurance in which the first Claim is made against the Insured, irrespective of the number of claimants or the period over which Claims may thereafter be made against the Insured arising out of such Bodily Injury.



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## **EXCLUSIONS TO SECTION 3 & 4**

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 4 in respect of any liability or claim arising out of, caused by, resulting from or in any way involving any of the following:

- (1) any act or omission which constitutes a criminal offence.
- (2) any Human Clinical Trial performed without the informed written consent of each Research Subject obtained prior to the participation of such Research Subject(s) in such Human Clinical Trial.
- (3) any act, error, omission, event, Occurrence or Human Clinical Trial happening prior to the Retroactive Date.
- (4) any circumstances which the **Insured** was, or ought to have been, aware might give rise to a **Claim** prior to the inception of this **Policy**.
- (5) any act, error or omission which constitutes or involves a breach of, or failure to comply with, the terms of the protocol governing the Human Clinical Trial.
- (6) any advice, design, specification or professional services provided for a fee (or provided in circumstances where a fee would normally be charged).

#### SECTION 5 - ERRORS AND OMISSIONS LIABILITY



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### "CLAIMS MADE AND NOTIFIED" BASIS

#### COVER

The **Underwriters** shall, subject to the terms, conditions, **Limits of Liability** and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) legal liability for damages in respect of any Claim arising solely by reason of any negligent act, negligent error or negligent omission happening within the Policy Territory and in the course of the professional conduct of the Business by the Insured;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) Legal Costs in connection with paragraph (1) above,

provided that the Claim in respect of such liability is first made against the Insured during the Period of Insurance and is notified to the Underwriters in writing during the Period of Insurance.

#### **EXCLUSIONS TO SECTION 5**

- (1) any act, error, omission, event or Occurrence happening prior to the Retroactive Date.
- (2) any circumstances which the **Insured** was, or ought to have been, aware might give rise to a **Claim** prior to the inception of this **Policy**.
- (3) any neglect, error or omission by the Insured to effect or maintain insurance or to provide finance or advice on financial matters.
- (4) any insolvency of the Insured.
- (5) any neglect, error or omission by the Insured in the preparation of estimates of cost.
- (6) any costs of replacing and/or restoring documents which have been lost, mislaid, damaged or destroyed.
- (7) any costs or expenses incurred for the recall, withdrawal, inspection, removal, repair, alteration, replacement or reinstatement or amounts claimed for loss of use of Products, Pharmaceuticals, Medical Devices or contract work executed by or for the Insured or of any property of which such form a part.
- (8) any non-delivery or late delivery of Products or non-completion of works or operations.
- (9) any Cross Liabilities.

Please be aware the above exclusions are section specific and do not include the specific policy exclusions