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Affinity Healthcare – Independent Practitioners



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INTRODUCTION

Thank **You** for choosing CNA Hardy for **Your** insurance. The **Schedule, Policy** wording and any applicable endorsements should be read together as one document which represents the contract between **You** and **Us**. This is a legal document which should be kept in a safe place and which sets out what is and isn't covered by **Us**.

Please read this document including any attaching endorsements carefully. If **You** have any questions or if this document does not meet **Your** needs, please contact **Your** broker or agent who will be pleased to help **You**.

Information You have declared to Us

To allow **Us** to set the premium, terms, conditions and exclusions of this **Policy**, **We** have relied on information **You** have provided to **Us**. **You** have a duty to make a fair presentation to **Us**. This means **You** must ensure **You** have:

1. Informed **Us** of any material circumstance that **You** know or ought to know, or anyone responsible for **Your** insurances knows or ought to know, in a way that is reasonably clear and accessible to **Us**; and
2. Answered accurately any questions **We** have asked **You**; and
3. Checked that any information **You** do provide is correct.

Please be aware, if **We** discover that **You** have provided **Us** with false information knowing **You** are in breach of this duty, or not caring whether **You** are in breach of the duty, **We** have a right to treat this insurance as if it never existed, decline all **Claims** and keep the premium.

For a **Claim** to be covered it must be made against **You** or **Your Employees** during the **Period of Insurance** and notified to **Us** in accordance with the Policy Conditions.

If these documents do not meet **Your** needs, please contact **Your** broker or agent.

The basis of the cover We provide to You

In consideration of **Your** payment of premium to **Us** in accordance with the **Policy** condition 'Administrative Conditions' and in reliance upon any information **You** have provided **Us** with, **We** agree to provide insurance to **You** on a **Occurrence** basis for **Claims** arising from an **Occurrence** happening in connection with the rendering of **Healthcare Services** during the **Period of Insurance** or which are treated as an **Occurrence** during the **Period of Insurance** in accordance with the Policy Conditions and in the manner and to the extent provided in this **Policy**, subject to all terms, conditions and exclusions of the **Policy** and provided that:

1. **Our** liability shall not exceed the applicable limits as set out in the **Policy**, except where agreed by **Us** in writing and incorporated into this **Policy**; and
2. **You** will be liable to pay the amount specified in the **Schedule** and throughout this **Policy** as the **Excess**.

Important contact details

You will discover several contact details referenced throughout this **Policy**. **You** should read the relevant section of the **Policy** alongside these details, however, **We** have also provided a non-exhaustive list below, for ease.

As above, any questions regarding the cover provided under this **Policy** please refer to **Your** broker or agent.

Claims or Circumstance Notification:	Healthcare Claims, 20 Fenchurch Street, London, EC3M 3BY; ClaimsUKHealthcare@cna Hardy.com
Complaints (Claims):	Claims Director, Claims Department (Healthcare), 20 Fenchurch Street, London, EC3M 3BY; Tel: 020 7743 6800; ClaimsUKHealthcare@cna Hardy.com
Complaints (Other):	Regulatory Affairs Director, 20 Fenchurch Street, London, EC3M 3BY; Tel: 020 7743 6800; Complaints@cna Hardy.com
Data Protection Queries:	Data Protection Officer, General Counsel Department, 13th Floor, 20 Fenchurch Street, London, EC3M 3BY; DataProtectionOfficer@CNAHardy.com
Medico-Legal Advice Line:	Tel: 0333 043 1318 (operated by Connexus on Our behalf)

INSURING CLAUSES

Cover in respect of each insuring clause is on a '**Occurrence**' basis. This means that the **Policy** will pay out for a valid **Claim** arising from an **Occurrence** happening in connection with the rendering of any **Healthcare Services** during the **Period of Insurance**. We will also indemnify each person comprising **You** and **Your Employees** in respect of any cross liability in the same manner and to the same extent as if a separate **Policy** had been issued to each person, provided that the total amount **We** shall be liable to pay in respect of all persons shall not exceed the **Limit of Indemnity** as set out in the **Schedule** and the **Excess** shall apply to each individual separately and individually.

Cover under this **Policy** is subject to the **Limit of Indemnity** as set out in the **Schedule** and in Insuring Clauses and Endorsements section of the Policy Conditions.

INSURING CLAUSE A – Medical Professional Liability

We will indemnify **You** and **Your Employees** in respect of **Costs** and **Damages** which **You** or **Your Employees** will be legally liable to pay in respect of any **Claim** for **Bodily Injury** in relation to any actual or alleged negligent act, error or omission of **You** or **Your Employees** happening on or after any applicable **Retroactive Date** in connection with the rendering of any **Healthcare Services** or **Good Samaritan Acts** or **Voluntary Acts** anywhere within the **Territorial Limits**, during the **Period of Insurance** and reported to **Us** in accordance with the **Claims Conditions**.

Specific Extensions in relation to Insuring Clause A – Medical Professional Liability:

- a. Abuse and Molestation
- b. Extended Reporting Period – Maternity, Paternity, Adoption, Career Break or Sabbatical Leave
- c. Extended Reporting Period – Permanently Unfit for Work, Retirement or Death
- d. Good Samaritan Acts Performed Outside of Territorial Limits
- e. Medical Professional Liability for Clinical Trials
- f. Medical Professional Liability for Medical Products
- g. Regulatory Hearing and Inquest Costs
- h. Retroactive Clarification Clause

INSURING CLAUSE B – Professional Indemnity (Financial Loss)

We will indemnify **You** in respect of **Costs** and **Damages** which **You** will be legally liable to pay in respect of any **Claim**, other than for **Bodily Injury**, in relation to any actual or alleged negligent act, error or omission of **You** or **Your Employees** in the rendering of **Healthcare Services** happening on or after any applicable **Retroactive Date** in the course of **Your** business anywhere within the **Territorial Limit** during the **Period of Insurance** and reported to **Us** in accordance with the **Claims Conditions**.

Specific extensions in relation to Insuring Clause B – Professional Indemnity (Financial Loss):

- a. Breach of Confidentiality
- b. Data Protection Defence Costs
- c. Dishonesty of Employees
- d. Libel and Slander
- e. Loss of Documents

INSURING CLAUSE C – Public Liability

We will indemnify **You** and **Your Employees** in respect of **Costs** and **Damages** which **You** or **Your Employees** will be legally liable to pay in respect of any **Claim** arising from accidental:

1. **Bodily Injury**; or
2. **Property Damage**,

in connection with **Your** business as provided that –

1. Such **Bodily Injury** is not to any of **You** or **Your Employees** in the course of employment by **You** or to any patient, customer or **Research Subject** except for legal liability arising solely from an actual or alleged public liability **Occurrence** happening in connection with **Your** business as set out above; and
2. Such **Bodily Injury** does not arise from the rendering by **You** or **Your Employees** of any **Healthcare Services** or **Good Samaritan Acts** or **Voluntary Acts**; and
3. Such **Property Damage** is not to any **Property** owned by **You** and/or in the custody or control of **You** or **Your Employees** other than **Property** belonging to any of **Your Employees** or to a visitor; and
4. Such **Bodily Injury** or **Property Damage** arises from an **Occurrence** happening on or after any applicable **Retroactive Date** and anywhere within the **Territorial Limits**, during the **Period of Insurance** and reported to **Us** in accordance with the **Claims Conditions**.

5. Such **Bodily Injury** or **Property Damage** is not caused by, through or in connection with any **Product**.

The following Specific Extensions apply to Insuring Clause C – Public Liability:

- a. Defective Premises (applicable in England, Wales and Republic of Ireland only)

INSURING CLAUSE D – Products Liability

We will indemnify **You** and **Your Employees** in respect of **Costs** and **Damages** which **You** or **Your Employees** will be legally liable to pay in respect of any **Claim** arising from accidental:

1. **Bodily Injury**; or
2. **Property Damage**,

in connection with **Your** business and caused by through or in connection with any **Product** provided that -

1. Such **Bodily Injury** is not to any of **You** or **Your Employees** in the course of employment by **You** or to any patient, customer or **Research Subject** except for legal liability arising solely from an actual or alleged products liability **Occurrence** happening in connection with **Your** business as set out above; and
2. Such **Bodily Injury** does not arise from the rendering by **You** or **Your Employees** of any **Healthcare Services** or **Good Samaritan Acts** or **Voluntary Acts**; and
3. Such **Property Damage** is not to any **Property** owned by **You** and/or in the custody or control of **You** or **Your Employees** other than **Property** belonging to any of **Your Employees** or to a visitor; and
4. Such **Bodily Injury** or **Property Damage** arises from an **Occurrence** happening on or after any applicable **Retroactive Date** and anywhere within the **Territorial Limits** during the **Period of Insurance** and reported to **Us** in accordance with the **Claims Conditions**.

POLICY EXTENSIONS

These specific and general **Policy** extensions are subject to the combined **Limit of Indemnity** and **Excess** stated on the **Schedule** of this **Policy**.

Specific Extensions

Abuse and Molestation

This **Policy** extension shall only apply to Insuring Clause A – Medical Professional Liability.

Cover in respect of the Extension is provided on a 'claims made' basis. This means that cover applies in respect of a valid **Claim** made during the **Period of Insurance**

Notwithstanding the 'Abuse or Molestation' exclusion forming part of this **Policy**, **We** shall indemnify **You** against liability for **Costs** in respect of any **Claim** alleging **Abuse or Molestation** by **You** or **Your Employees** up until **Abuse or Molestation** is admitted by **You** or an adverse finding is made against **You**, provided that:

1. **We** shall not be liable for **Costs** in respect of alleged **Abuse or Molestation**:
 - a. committed prior to the **Retroactive Date** stated in the **Schedule**; or
 - b. where there has been any admission by **You** or an adverse finding against **You** in legal proceedings in respect of **Your** liability for **Abuse or Molestation** by **You** or **Your Employees**; or
 - c. where any of **Your Employees** which are the subject of the **Claim** have perpetrated, instigated or connived towards such **Abuse or Molestation** with **Your** knowledge or support; or
 - d. where the perpetrator of the **Abuse or Molestation** was **Your Employee** whom **You** knew or ought upon reasonable enquiry, including but not limited to in the process of hiring, acceptance, vetting, supervision or retention of such employee, to have known had committed or been cautioned for or been convicted of **Abuse or Molestation** or placed on any sexual offenders register.
2. **Our** liability under this extension shall not exceed the sub-**Limit of Indemnity** stated in the **Schedule** which shall apply in respect of any one **Claim** and in the aggregate during the **Period of Insurance**.
3. **We** shall not be liable for the **Excess** as stated in the **Schedule**.
4. **We** shall not be liable for any fines, penalties or any **Criminal Prosecution Defence Costs**.
5. All **Claims** in respect of **Abuse or Molestation** perpetrated by one person shall be deemed to have been made in the **Period of Insurance** in which the first **Claim** was made or is deemed to have been made as a result of a notification of **Circumstances** in accordance with the **Claims Conditions** in respect of that person.
6. All **Claims** made by an individual or by a group of individuals together in respect of any **Abuse or Molestation** which may have taken place after the **Retroactive Date** stated herein shall be regarded as a single **Claim** which will be deemed to have been made in the **Period of Insurance** in which the first **Claim** was made by such individual or group of individuals.

Breach of Confidentiality

This **Policy** extension shall only apply to Insuring Clause B – Professional Indemnity (Financial Loss).

We shall indemnify **You** for **Claims** made against **You** or **Your Employees** arising from any breach of confidentiality in respect of the conduct of **Your Healthcare Services** rendered during the **Period of Insurance** provided that **We** shall not be liable under this extension for any **Claims** in respect of or arising from:

1. libel or slander;
2. any intentional breach of any duty of confidentiality or rights of privacy;
3. the loss of any **Documents** which are the **Property** of or are entrusted to **You** and **Your Employees** or the **Costs** and **Damages** incurred by **You** or **Your Employees** in replacing or restoring such **Documents**;
4. any infringement of the **Data Protection Laws**.

Our liability under this extension shall not exceed the sub-**Limit of Indemnity** stated in the **Schedule** of this **Policy**.

Data Protection Defence Costs

This **Policy** extension shall only apply to Insuring Clause B - Professional Indemnity (Financial Loss).

We shall indemnify **You** in respect of reasonable legal costs and reasonable expenses consented to in advance by **Us** in the defence of any prosecution for alleged offences under sections 119, 144, 148, 170, 171, 173 and 184 of the Data Protection Act 2018 or equivalent offences under predecessor legislation, provided that:

1. the act, error or omission giving rise to such prosecution shall have been committed by **You** and/or **Your Employees** in the course of **Your Healthcare Services** and within the **Territory**;
2. such prosecution is commenced during the **Period of Insurance** and notified in accordance with the relevant terms and conditions of the **Policy**;
3. **We** shall have no liability to pay legal costs and expenses incurred subsequent to a plea or finding of guilt on the part of **You** and/or **Your Employees** or in the event that Counsel (or where there is no Counsel, the lawyers appointed in the defence of the prosecution) should advise that there are no reasonable prospects of successfully defending the proceedings, except for costs incurred solely for the purpose of making a plea in mitigation before sentencing or costs incurred in making an appeal if Counsel (or where there is no Counsel, the lawyers appointed in the defence of the prosecution) should advise that the prospects of a successful appeal following a finding of guilt are reasonable.

Defective Premises (applicable in England, Wales and Republic of Ireland only)

This **Policy** extension shall only apply to Insuring Clause C – Public Liability.

We will indemnify **You** against legal liability in respect of **Bodily Injury** or **Property Damage** arising by virtue of the Defective Premises Act 1972 or any amendment or re-enactment, in connection with any premises formerly used for the purposes of **Your** business and disposed of by **You**.

However, this indemnity shall not apply in respect of any liability, loss of or damage to, or for any costs or expenses incurred in repairing replacing or making any refund in respect of any such premises.

Dishonesty of Employees

This **Policy** extension shall only apply to Insuring Clause B - Professional Indemnity (Financial Loss).

We shall indemnify **You** for **Your** and/or **Your Employees'** liability for compensatory damages, claimant's legal costs and expenses and defence **Costs** arising out of any dishonest or fraudulent act or omission, committed by **Your Employees** in connection with **Your** business carried on, by, or on behalf of, **You** and/or **Your Employees**, within the **Territory**, during the **Period of Insurance** and notified in accordance with the relevant terms and conditions of the **Policy**, provided that:

1. **You** and/or **Your Employees** will, by any means and at no cost to **Us**, seek to recover or obtain reimbursement of all such monies;
2. no indemnity shall be provided to any person committing, condoning or ignoring such dishonest or fraudulent act or omission;
3. **You** and/or **Your Employees** shall take reasonable steps to prevent dishonest and fraudulent acts and omissions;
4. **We** shall be entitled to deduct from any payment to be made by **Us** under this clause, or to be reimbursed in respect of any payment already made by **Us**, any monies:
 - a. recovered or reimbursed pursuant to Part 1 of this clause;
 - b. which would be due to, or which are held by **You** and/or **Your Employees** and belong to, any person who committed condoned or ignored the dishonest or fraudulent act or omission.

Nothing in this extension shall preclude **Us** from exercising any right of subrogation against any person committing, condoning or ignoring such dishonest or fraudulent act or omission.

Our liability under this extension shall not exceed the sub-Limit of Indemnity stated in the **Schedule** of this **Policy**.

Hibernation Cover – Maternity, Paternity, Adoption, Career Break or Sabbatical Leave

This **Policy** extension shall only apply to Insuring Clause A - Medical Professional Liability.

In the event of **Your** maternity, paternity, adoption, career break or sabbatical leave, provided that this **Policy** is neither renewed nor replaced at the end of the expiring **Period of Insurance** with insurance that covers substantially the same risk exposure as this **Policy**, **You** will be entitled to a hibernation period of 12 (twelve) months for Insuring Clause A 'Medical Professional Liability' of this **Policy**.

You will only be entitled to a hibernation period for **Your** maternity, paternity, adoption, career break or sabbatical leave provided that:

- a. **You** have notified **Us** in advance and in writing that **You** are intending to take maternity, paternity, adoption, career break or sabbatical leave;
- b. **You** have notified **Us** of the date during the **Period of Insurance** of commencement of **Your** period of leave; and
- c. **You** notify **Us** in advance of the date of **Your** return to practice.

The hibernation period begins on the date notified to **Us** of the commencement of **Your** maternity, paternity, adoption, career break or sabbatical leave and ends at 11.59.p.m. G.M.T. on the first anniversary of that date, or, if earlier, at the time on the effective date on which **You** obtain insurance that covers substantially the same risk exposure as Insuring Clause A - Medical Professional Liability of this **Policy**.

The entitlement to trigger the hibernation period lapses upon the cancellation of this **Policy** or the end of the expiring **Period of Insurance**.

The application to trigger the hibernation period must be received by **Us** prior to the end of the expiring **Period of Insurance**. It shall then be recorded by **Us** as an endorsement to this **Policy**.

During the hibernation period **You** may continue to notify **Us** of **Claims**, but only **Claims** based on any act, error or omission committed or alleged to have been committed prior to the date of commencement of **Your** maternity, paternity, adoption, career break or sabbatical leave, and such **Claims** will be deemed to be first notified to **Us** during the expiring **Period of Insurance**.

The coverage afforded under this extension shall only apply to **Claims** against **You**. There shall be no coverage under the extension for **Claims** made solely against any of **Your Employees**.

Good Samaritan Acts Performed Outside of Territorial Limits

This **Policy** extension shall only apply to Insuring Clause A – Medical Professional Liability.

We agree to indemnify **You** against all **Claims** arising from an actual or alleged negligent act, error or omission happening on or after any applicable **Retroactive Date** as a result of any **Good Samaritan Act** subject to the **Limit of Indemnity** stated on the **Schedule** of this **Policy**.

Leased Premises

This **Policy** extension shall only apply to Insuring Clause C – Public Liability.

We will indemnify **You** against legal liability for **Property Damage** to premises or fixtures or fittings thereof which are leased to **You**.

However, this indemnity shall not apply in respect of any liability for **Property Damage** if the liability is assumed under any tenancy or other agreement and would not have attached in the absence of such agreement.

We will indemnify **You** in relation to this extension only up to the amount noted in the relevant sub-**Limit of Indemnity** as shown in the **Schedule**.

Libel and Slander

This **Policy** extension is applicable to Insuring Clause B – Professional Indemnity (Financial Loss).

We agree to indemnify **You** and/or **Your Employees** against all sums which **You** shall become legally liable to pay as **Costs** and **Damages** as a result of any **Claim** made against **You** and/or **Your Employees** arising during the **Period of Insurance** for **Libel and Slander** by reason of words written or spoken by **You** and/or **Your Employees**.

We will indemnify **You** in relation to this extension only up to the amount noted in the relevant sub-**Limit of Indemnity** as shown in the **Schedule**.

Loss of Documents

This **Policy** extension is applicable to Insuring Clause B - Professional Indemnity (Financial Loss).

We will indemnify **You** for **Costs** necessarily incurred by **You** and/or **Your Employees** with **Our** prior written consent for the restoration or replacement of any **Documents** which is necessary for the performance of **Your Healthcare Services** following accidental or unintended loss, distortion, erasure or destruction of any **Documents** provided that:

- a. There shall be no indemnity in respect of any **Documents** kept in magnetic or electronic form unless such **Documents** are duplicated and stored at separate premises as a backup; and
- b. This extension does not apply to any negotiable instrument of any nature.

We will indemnify **You** in relation to this extension only up to the amount noted in the relevant sub-**Limit of Indemnity** as shown in the **Schedule**.

Medical Professional Liability for Clinical Trials

This **Policy** extension shall only apply to Insuring Clause A - Medical Professional Liability.

Notwithstanding the Policy exclusion 'Clinical Trials', **We** shall indemnify **You** against liability arising from actual or alleged **Bodily Injury** in relation to any actual or alleged negligent act, error or omission in connection with the rendering of **Healthcare Services** during a **Clinical Trial**.

Medical Professional Liability for Medical Products

This **Policy** extension shall only apply to Insuring Clause A - Medical Professional Liability.

We shall indemnify **You** against liability arising from actual or alleged **Bodily Injury** in relation to any actual or alleged negligent act, error or omission in connection with the rendering of **Healthcare Services** involving the use of **Products** including off label products when prescribed in accordance with NICE Guidelines, HIQA Guidelines or local equivalent.

Regulatory Hearing and Inquest Costs

This **Policy** extension is applicable to Insuring Clause A - Medical Professional Liability only.

Cover in respect of the Extension is provided on a 'claims made' basis. This means that cover applies in respect of a valid **Claim** made during the **Period of Insurance**

Irrespective of **Bodily Injury**, **Costs** covered under this **Policy** shall include **Regulatory Hearing and Inquest Costs**, provided that,

- a. such hearing or inquest arises out of the provision of **Healthcare Services** or a **Good Samaritan Act** or a **Voluntary Act**; and
- b. is initiated by a third party or where directly or indirectly initiated by **You** is initiated in good faith and in the interest of patient safety;

We will not indemnify you under this extension for any **Costs** or expenses arising in relation to any criminal investigation or for any **Criminal Proceedings Defence Costs**.

We will indemnify **You** in relation to this extension only up to the amount noted in the relevant sub-**Limit of Indemnity** as shown in the **Schedule**.

Temporary Overseas Cover

This Policy extension shall only apply to Insuring Clause A – Medical Liability.

We agree to indemnify **You** against all **Claims** arising from an actual or alleged negligent act, error or omission happening on or after any applicable **Retroactive Date** as a result of any **Healthcare Services** or **Voluntary Acts** outside of the **Territorial Limits**, provided that **You** are not outside of the **Territorial Limits** for more than 30 (thirty) days during the **Period of Insurance** stated on the **Schedule**.

However, this indemnity shall not apply whilst **You** are in the United States of America.

General Extensions

Prior Acts Cover

We will indemnify **You** and **Your Employees** in respect of **Costs** and **Damages** which **You** or **Your Employees** will be legally liable to pay in respect of any **Claim**:

1. first made against **You**; and
2. immediately reported to **Us** in writing during the **Reporting Period**

in respect of liability arising from **Healthcare services** undertaken during the **Prior Acts Period**.

For the avoidance of doubt the **Claim** must:

- a. result from the providing of or failure to provide **Healthcare Services** during the **Prior Acts Period**; and
- b. cause **Bodily Injury** or **Damage** as defined in this **Policy**.

We will not indemnify **You** for Claims arising out of **Healthcare Services**:

1. from which **You** could expect that a **Claim** would result,
2. which is the subject of any pending **Claim** or proceedings, at the point of first inception of the **Policy**
3. or which is known or ought to be known to **You** prior to the inception of this **Policy**.

Vicarious Liability

We will indemnify **You** in respect of **Costs** and **Damages** which **You** will be legally liable to pay in respect of any **Claim** against **You** under any of the Insuring Clauses in relation to any actual or alleged negligent act, error or omission covered under Insuring Clauses A or B or any **Bodily Injury** or **Property Damage** arising from an **Occurrence** covered under Insuring Clauses C or D happening on or after any applicable **Retroactive Date** in respect of **Your Employees** acting on behalf of or in conjunction with **You** where **You** are vicariously liable or **Your** liability is due to a non-delegable duty of care, provided that any such **Claim** is in connection with the rendering of any **Healthcare Services** anywhere within the **Territorial Limits** during the **Period of Insurance** and reported to **Us** in accordance with the conditions of this **Policy**.

POLICY EXCLUSIONS

The following exclusions are applicable to the **Policy** as a whole.

We will not indemnify **You** for **Damages**, **Costs**, or **Regulatory Hearing and Inquest Costs** based on or arising out of:

Abuse or Molestation

any loss based on, arising out of or in any way connected to **Abuse or Molestation**, save to the extent that any loss is indemnified under the Abuse and Molestation extension.

Aircraft

any aircraft or other aerial device hovercraft or watercraft.

Asbestos

asbestos, asbestos fibres or any derivatives of asbestos, whether airborne as a fibre or carried or transmitted on clothing or inhaled or ingested or transmitted by any other means, contained in or forming part of any building, building material or insulating material including any product containing asbestos, asbestos fibres or any derivatives of asbestos except for the rendering of **Healthcare Services**, **Good Samaritan Act** or **Voluntary Act** under Insuring Clause A - Medical Professional Liability to any patient injured or ill as a direct result of asbestos.

Claims made against You and/or Your Employees

Any **Claims** made against **You** and/or **Your Employees** by any:

1. entity participating in a joint venture with **You** and/or **Your Employees**, other than any of **Your** and/or **Your Employees'** legal liability attributable only to any act, error or omission;
2. parent company, ultimate holding company or subsidiary company;
3. legal or natural person or entity having or acquiring any financial executive or controlling interest in the operation of **Your Healthcare Services**;
4. entities in which **You** or any of **Your** directors, officers, partners, or members has any financial executive or controlling interest.

Clinical Trials

any liability

1. in respect of errors in the and/or failure to comply with the legal requirements for planning design or implementation of a **Clinical Trial**;
2. any drugs medical devices or similar products or medical devices used or tested in a **Clinical Trial** being unsafe or ineffective;
3. otherwise arising from **Your** sponsoring, funding or organisation of a **Clinical Trial**, or any joint venture with another natural person, company or association to sponsor, fund or organise a **Clinical Trial**;
4. that is or would normally be insured under a clinical trials insurance policy, except insofar as cover is provided under the Medical Professional Liability for Clinical Trials extension.

Contractual Liability

any actual or alleged liability of **You** and/or **Your Employees** under any oral or written contract or agreement, including but not limited to express warranties or guarantees and any liability of any party assumed by **You** and/or **Your Employees** under any oral or written contract or agreement except insofar as any liability would have arisen to the same extent in the absence of such oral or written contract.

Criminal Prosecution Defence Costs

any **Criminal Prosecution Defence Costs**.

Cyber Liability

1. Notwithstanding any provision to the contrary within the **Policy** or any endorsement and except as provided in paragraph 2 below, the **Policy** does not cover any actual or alleged loss, damage, liability, claim, fine, penalty, cost or expense of whatsoever nature, including notification costs, crisis consultancy costs, credit monitoring expenses, replacement of actual credit or payment cards, forensic expenses, public relations expenses or legal advice and services, directly or indirectly caused by, contributed to by, resulting from, arising out of or in connection with any:
 - 1.1 **Cyber Act** or **Cyber Incident**, including but not limited to, any action taken in controlling, preventing, suppressing or remediating any **Cyber Act** or **Cyber Incident**; or
 - 1.2 **Data Breach**.
2. However, any otherwise covered **Bodily Injury** caused by, contributed to by, resulting from, arising out of or in connection with any **Cyber Act**, **Cyber Incident** or **Data Breach** will be payable subject to the **Policy** terms, conditions and limitations.

For the purposes of paragraph 2 above **Bodily Injury** shall mean physical injury (including death at any time resulting therefrom), including any sickness, disease, or disability resulting from such physical injury. For the purposes of paragraph 2 above **Bodily Injury** does not include mental injury, shock, mental anguish, emotional distress or mental disease or illness unless consequential upon physical injury.

Data Protection Act and GDPR

any actual or alleged breach of **Data Protection Laws** save to the extent any loss is indemnified under the Data Protection Defence Costs extension.

Delay of Product

any performance delay and/or delivery delay of a **Product**.

Directors' and Officers' Liability

any directors' and officers' liability, including any liability based on or arising out of **Your** role as a director, officer or trustee of any company or association.

Discrimination, humiliation or harassment

any discrimination, humiliation or harassment, that includes but shall not be limited to a **Claim** based on an individual's race, creed, colour, age, gender, national origin, religion, disability, marital status or sexual preference.

Employers' Liability

any employers' liability or employment practices liability, including any actual or alleged physical or mental injury to, or any actual or alleged breach of, any employment laws in respect of **Your Employees** or any other person whose work or service is directed or controlled by **You** caused by or arising out of their engagement by **You**. This clause does not prevent **You** from being indemnified under Insuring Clause A - Medical Professional Liability and Insuring Clause B – Professional Indemnity (Financial Loss) if **Your** patient or client also happens to be **Your Employee** or any other person whose work or service is directed or controlled by **You**.

Excluded Territories

any liability to pay **Claims** or benefit hereunder in relation to any entity or individual domiciled in, or any **Claim** or activity involving any entity or person domiciled in or involving the territory of:

1. Cuba;
2. Iran;
3. North Korea;
4. Syria;

5. the Crimea Region of Ukraine.

Notwithstanding the **Territorial Limits** applicable to the **Policy**, all such territories stated above are excluded from the **Policy** and no cover whatsoever shall be deemed given under this **Policy** and no business activity being undertaken in that territory or the provision of any service to or shipment of any goods to, from or within that territory will be covered by this **Policy**.

Fines or Penalties

any criminal or civil fines or penalties or any punitive, aggravated additional or exemplary **Damages**.

Intellectual property rights

any defamation or malicious falsehood and/or any breach or infringement of intellectual property rights including patent, copyrights, trademarks, or any deliberate intent to cause harm. For the avoidance of doubt, this exclusion does not affect the **Libel and Slander** extension in respect of Insuring Clause B.

Intoxicants or Narcotics

arising out of the performance of **Healthcare Services** whilst under the influence of intoxicants or narcotics except insofar as cover is provided under the Vicarious Liability extension.

Insolvency

Your or **Your Employees'** insolvency, bankruptcy or de facto insolvency.

Joint Ventures

any liability arising from any joint ventures or acting in concert or association with any other party other than any legal liability of **You** or **Your Employees** attributable only to any act, error or omission of **You** or **Your Employees** in any such venture or association which is otherwise covered under this **Policy**.

Known Claim or Circumstance

any:

1. **Circumstance** or **Claim** notified under any insurance which was in existence prior to the inception of this **Policy**;
2. **Claim** made threatened or initiated against **You** and/or **Your Employees** prior to the inception of this **Policy**;
3. **Circumstance** known to **You** and/or **Your Employees** or which **You** and/or **Your Employees** might reasonably have known at the inception of this **Policy**, would or might reasonably be expected to give rise to a **Claim**;
4. **Circumstance** or **Claim** which has been or should reasonably have been notified to **Us** in the proposal.

Maintenance of Insurance

any actual or alleged failure to arrange and/or maintain any insurance or failure to make any other indemnity arrangement.

Malicious or Reckless Act

any fraudulent, dishonest, criminal, illegal, malicious or reckless act or omission by **You** and/or **Your Employees** whether acting alone or in collusion with other persons, however this shall not affect **Your** cover under this **Policy** provided under the Vicarious Liability extension for **Your** liability arising from such acts by **Your Employees**, provided always that **You** had no knowledge of and did not condone any such fraudulent, dishonest, criminal, illegal, malicious or reckless act or omission.

Nuclear

radiation or radioactive contamination, whether directly or indirectly caused and/or occurring or arising in any form including but not limited to:

1. all forms of radioactive contamination of persons and/or **Property**;
2. any radiation or radioactive contamination from any nuclear fuel, nuclear material including spent fuel, or any nuclear waste at any time possessed, handled, used, processed, stored, transported or disposed of by **You** or on **Your** behalf;
3. any radiation or radioactive contamination in the provision of **Your** services, materials, parts or equipment, any other hazardous properties of the above including radioactive toxic or explosive properties of any nuclear assembly or nuclear component thereof;

except for the rendering of **Healthcare Services**, **Good Samaritan Act** or **Voluntary Act** covered under Insuring Clause A - Medical Professional Liability, to any patient injured or ill as a result of any radiation or radioactive contamination.

Other Insurance

any indemnity to which **You** are entitled under any other insurance and/or indemnity arrangement for any **Claim** except that if there is or would be but for the existence of this **Policy** any other more specific insurance and/or other indemnity arrangement covering the same **Claim** or **Occurrence** or any part thereof, the relevant Insuring Clause of this **Policy** shall only contribute in excess of such other insurance and/or indemnity arrangement.

Pharmaceutical Products

the testing or other use of any **Product, Pharmaceutical Drug, Medical Device, Bio Science Product**, food, or similar item made of or containing the following:

1. Dexfenfluramine;
2. Fenfluramine;
3. Phentermine;
4. Thalidomide;
5. Silicone Gel used as an injection or as a part of an implantable device;
6. Accutane;
7. Birth Control devices and medications;
8. Diethylstilbestrol (DES);
9. Swine Flu vaccine;
10. Phenylpropanolamine;
11. Metoclopramide;
12. any intra-articular pain pump or continuous infusion device to deliver any type of medication to the patient;
13. implantable mesh products used in anterior or posterior pelvic floor repair;
14. any Metal-on-Metal (use of femoral head articulating in conjunction with a metal liner or metal cup) hip replacement systems, including components thereof;
15. testosterone;
16. **Opioids**;

except that this exclusion shall not apply in respect of Insuring Clause A - Medical Professional Liability.

Pollution

any actual or threatened **Pollution** or any requirement for **You** and/or **Your Employees** to deal with any **Pollution** except for the rendering of **Healthcare Services, Good Samaritan Act** or **Voluntary Act** under Insuring Clause A - Medical Professional Liability to any patient injured or ill as a direct result of any **Pollution**.

Product Recall

based on or arising out of any goods recall or **Product** recall and/or withdrawal or any costs or expenses incurred in repairing replacing recalling withdrawing or making any refund in respect of any suspected or known **Defect** in any **Products** or goods.

Product without Regulatory Approval

based on or arising out of any **Product** that does not have appropriate regulatory approval for the purpose for which it is being, or was, used. This **Policy** exclusion does not apply to the Medical Professional Liability for Medical Products extension.

Property Damage

any **Property Damage**, including loss of use of **Property**, that is not caused by physical damage.

Sanctions

any trade or activity which is subject to any applicable economic, political or trade sanction, prohibition or restriction. **We** shall not be deemed to provide cover, be liable to pay any damage or provide any benefit hereunder to the extent that the provision of such cover, payment of such damage or provision of such benefit would expose **Us** or any member of **Our** group to any applicable economic, political or trade sanction, prohibition or restriction. **We** are obligated to comply with all applicable United Kingdom, United Nations, European Union and US (including those imposed by the Office of Foreign Asset Control) financial restrictions, measures and sanctions, which shall all form part of this clause.

Temporary Premises

any premises including contents (not being premises leased or rented to **You**) which are temporarily occupied by **You** for the purpose of **Your** business except that this exclusion shall not apply in respect of **Claims** under Insuring Clause C – Public Liability when temporary premises are occupied for providing **Healthcare Services**.

Territorial Limits

any **Occurrence** or any actual or alleged negligent act, error or omission arising outside the **Territorial Limits** stated in the **Schedule**, or under the laws of countries outside such **Territorial Limits**, or for recognition or enforcement of a judgment obtained in such countries or under such laws whether by way of reciprocal agreement or otherwise. This **Policy** exclusion does not apply in respect of the 'Temporary Overseas' extension.

Vehicle

the ownership, possession or use while under **Your** control of any mechanically propelled vehicle except for the rendering of **Healthcare Services**, **Good Samaritan Act** or **Voluntary Act** under Insuring Clause A – Medical Professional Liability to any patient involving the use of a vehicle.

War, Terrorism and Pollution

any:

1. **Bodily Injury** or **Property Damage** that in whole or in part arises directly or indirectly out of one or more of the following;
 - a. Government action;
 - b. **War**;
 - c. **Terrorism** or any action taken to prevent or address actual or expected **Terrorism**;
2. Any loss cost or expense arising out of testing for, monitoring, cleaning up removing, containing, treating, detoxifying, neutralizing or disposing of or in any way assessing or responding to the effects of toxic infectious or radioactive matter distributed generated or released as a direct or indirect result of any event described in Paragraph 1 above regardless of any other cause or event that contributed concurrently, or in any sequence, to such injury, physical damage, physical loss, cost or expense.

Part 1 does not apply to **Bodily Injury** or **Property Damage** caused while rendering **Healthcare Services**, **Good Samaritan Act** or **Voluntary Act** following the conclusion of any **Terrorism**.

Workers' Compensation

any obligation **You** may have under workers' compensation, disability benefits, or unemployment compensation law, or any similar law or employment protection legislation and any liability directly or indirectly arising out of any **Claim** for breach of any duty owed by **You** as an employer to any person employed, or former person employed, or applicant for employment.

Wrongful or Unlawful Detention

any wrongful or unlawful detention in breach of the Mental Health Act 1983, the Human Rights Acts 1998 or any common law provision or any equivalent law in any jurisdiction.

POLICY CONDITIONS

These conditions apply to all operative Insuring Clauses, extensions and endorsements applicable to this **Policy**.

Claims Conditions

Your duties in the event of a **Claim**, **Occurrence** or **Circumstance**.

1. On discovery or receipt of any **Claim** or **Occurrence** which may be covered under any of the Insuring Clauses, **You** shall give written notice of such **Claim** to **Us** as soon as reasonably practicable after **You** first becomes aware of such **Claim** or **Occurrence**
2. On discovery of any **Circumstances**, **You** shall give written notice of such **Circumstances** to **Us** as soon as reasonably practicable.
3. Notice as required by paragraphs 1 and 2 above shall include:
 - a. details of what happened and the services and activities that **You** and/or **Your Employees** were performing at the relevant time; and
 - b. the nature of any, or any possible, **Bodily Injury**, **Property Damage** or **Damages**; and
 - c. how **You** and/or **Your Employees** first became aware of the **Claim** or **Circumstances**; and
 - d. all such further particulars as **We** may require.
4. Any **Claim** that may be made subsequently against **You** and/or **Your Employees** arising out of any **Circumstances** notified in accordance with paragraph 2 above shall be deemed for the purposes of this **Policy** to have been made on the date **We** first received such written notice of the **Circumstances**.
5. **You** and/or **Your Employees** shall forward to **Us** any communication or other documentation pertaining to **Proceedings**, and/or any process in connection with such **Proceedings** within 7 (seven) days of receipt.
6. **You** and/or **Your Employees** shall provide all information and assistance required by **Us**.
7. Neither **You** or **Your Employees** shall make any admission of liability nor make any offer and/or promise of payment and/or payment without **Our** prior written consent.

Defence of Claims

1. **We** shall have the right at any time, but not the obligation, to take over and conduct in the name of **You** and/or **Your Employees** the defence and/or investigation and/or settlement of any **Claim** and to prosecute at **Our** own expense and for **Our** own benefit any rights of recovery or subrogation against all other parties or persons.
2. At any time where the amount due or sought in relation to any **Claim** exceeds the applicable **Limit of Indemnity** **We** shall have the right to withdraw from any further investigation, defence, and/or settlement of said **Claim** upon payment of the said **Limit of Indemnity** and in that event **We** will have no further liability and/or obligation in relation to such **Claim**.
3. **We** shall be entitled at any time and by **Our** own discretion to pay **You** an applicable **Limit of Indemnity** less any **Costs** incurred by **Us**, or any lesser sums for which any **Claim** under any Insuring Clause of this **Policy** can be settled, and in that event **We** shall not be under any further liability to pay any other amount in respect of the relevant **Claim** or under the relevant Insuring Clause, as applicable.

Other Conditions

Administrative Conditions

1. Where the premium is calculated upon estimates furnished by **You**:
 - a. **You** shall keep an accurate record of all relevant particulars; and
 - b. **We** shall be allowed to inspect such records at all reasonable times; and
 - c. **You** shall within 1 (one) month from the expiry of each **Period of Insurance** supply to **Us** such particulars as **We** may require and the premium for such **Period of Insurance** shall be adjusted and the difference paid by or allowed to **You** as the case may be, subject to any minimum premium applicable.
2. **We** may at any time and solely at **Our** own discretion:
 - a. waive any of **Our** rights under any condition of this **Policy**; and/or
 - b. waive any requirement of or action to be undertaken by **You** and/or **Your Employees** under any condition of this **Policy**; and/or
 - c. accept notification of or continue to deal with any **Circumstances**, or any actual **Claims** as applicable, under this **Policy** notwithstanding any breach by **You** and/or **Your Employees** of any condition or part of this **Policy**,
except that no such waiver, acceptance or action by **Us** will waive or limit in any way any of **Your** and/or **Your Employees'** obligations, or imply or constitute any other waiver of **Our** rights in respect of any other condition of this **Policy** or any other **Claim**.

3. Where the context allows, any word or phrase appearing in **bold** and defined shall have such defined meaning wherever it may appear in this **Policy**.

Cancellation

We may cancel this **Policy** by giving **You** written notice, stating when, not less than 30 (thirty) days thereafter, such cancellation shall be effective. **We** shall then return premium to **You** on a pro rata basis provided that no **Claim** or **Circumstance** has been notified under this **Policy**.

You may cancel this **Policy** by giving **Us** written notice, stating when, not less than 30 (thirty) days thereafter, such cancellation shall be effective. **We** shall return premium to **You** on a pro rata basis to the total premium which would have been payable but for such cancellation provided that no **Claim** or **Circumstance** has been notified under this **Policy**.

Changes

None of the provisions of this **Policy** will be amended or modified except by written endorsement issued to form a part of this **Policy**.

Choice of Law and Jurisdiction

This **Policy** shall be governed by, and construed solely in accordance with, the laws of England, Wales and Republic of Ireland. The courts of England, Wales and Republic of Ireland shall have exclusive jurisdiction to settle any dispute arising out of or in connection with this **Policy**.

Clinical Staff

All clinical staff must hold an appropriate licence and must be registered with the appropriate body in the relevant jurisdiction.

Excess

You agree to pay the **Excess** amount to any party for any legal liability, arising out of any **Claim** which may be the subject of an indemnity under this **Policy**, before **We** shall be liable to make any payment for the said **Claim** under any operative Insuring Clause or endorsement of this **Policy**.

Fraud

If any benefit is obtained or attempted to be obtained under this **Policy** by way of any fraudulent means or devices by **You**, or anyone acting on **Your** behalf, then in accordance with the Insurance Act 2015 or other legislation **We** shall not be liable to pay the **Claim** and may terminate the **Policy** with effect from the time of the fraudulent act, retaining any premiums paid.

However, treating a contract as having been terminated does not affect **Your** or **Our** rights and obligations with respect to a relevant event (for example, the occurrence of a loss, the making of a **Claim**, or the notification of a **Circumstance**) occurring before the time of the fraudulent act.

Insuring Clauses and Endorsements

1. Subject to any applicable sub-limit or **Limit of Indemnity** **Our** liability under each operative Insuring Clause and endorsement of this **Policy** in any one **Period of Insurance** shall not exceed the **Limit of Indemnity** for each **Claim** / **Occurrence**, or the aggregate **Limit of Indemnity** for all **Claims** / **Occurrences**, stated in the **Schedule**. The aggregate **Limit of Indemnity** applies as a single aggregate limit in any one **Period of Insurance** in respect of all Insuring Clauses including any extension or endorsement regardless of the number of **Claims**, insureds, locations, judgments, awards, settlements or types of loss involved.
2. Where legal liability arises under more than one Insuring Clause extension or endorsement of this **Policy** in relation to any **Claim** in respect of the same **Occurrence** or actual or alleged negligent act, error or omission as applicable, **Our** total liability for such **Claim** under this **Policy** shall not exceed the highest per claim and annual aggregate **Limit of Indemnity** applicable to one Insuring Clause, regardless of whether legal liability arises under more than one Insuring Clause.
3. **Costs** and **Regulatory Hearing and Inquest Costs**, are only covered:
 - a. when expressly covered under an Insuring Clause and/or extension as set out above; and
 - b. when they are incurred with **Our** prior written consent.
4. In respect of Insuring Clause A and Insuring Clause B, **Costs** and **Regulatory Hearing and Inquest Costs** are included within each applicable **Limit of Indemnity** and any payment of **Costs** will correspondingly reduce the applicable **Limit of Indemnity** available for paying **Damages**.
5. In respect of Insuring Clause C and Insuring Clause D, **Costs** are in addition to each applicable **Limit of Indemnity** and any payment of **Costs** will not reduce the applicable **Limit of Indemnity** available for paying **Damages**.
6. For the purposes of this **Policy**, and including the application of any **Excess** or **Limit of Indemnity**, **Interrelated Claims** shall only ever constitute one **Claim** which shall be deemed to have been first made on the earlier of:
 - a. the date on which the earliest such **Claim** was first made, or
 - b. the first date valid notice was given under this **Policy** or under any prior policy by **You** to **Us** of any negligent act, error or omission or any **Occurrence** or **Circumstances**, including but not limited to, any situation, event or transaction which underlies any such **Claim**.

Material Changes

You must inform **Us** as soon as possible within 30 (thirty) days if **Your** entitlement to practise **Healthcare Services** is withdrawn, suspended, altered, restricted or amended by the General Medical Council, the Irish Medical Council, the Royal Pharmaceutical Society, the Pharmaceutical Society of Ireland or any government, regulatory, statutory, professional or supervisory authority, or if **You** are prevented from practising **Healthcare Services** by an order of any court or HCAFO322 – Affinity Healthcare

as a result of **Your** failure to renew any practising license or registration. If **You** so inform **Us**, we may elect, at **Our** discretion, to revise any definitions, terms, conditions, limitations, exclusions or endorsements in this **Policy** from the date of any such change to **Your** license or entitlement. Any such revisions will be recorded in an endorsement to this **Policy** and **We** will provide a copy to you within 10 (ten) days.

If there is any change to any material circumstance or other information **You** provided when applying for this **Policy** then **You** must inform **Us** in writing as soon as possible. If **You** are uncertain whether there has been a change to a material circumstance, then **You** should inform **Us** (whether directly or through **Your** insurance broker) of the change. If **You** so inform **Us**, and **We** reasonably consider that the change increases the likelihood of a **Claim** being made against **You**, **We** are entitled, at **Our** discretion, to charge an additional premium. Any such additional premium, and the due date for the additional premium, will be recorded in an endorsement to this **Policy**.

Premium Payment

It is a condition to **Our** liability under this **Policy** that the premium shall be paid in full by **You** to **Us**:

1. in accordance with the agreement between **You** and **Your** broker or agent; or
2. no later than 60 (sixty) calendar days of the commencement of the **Period of Insurance**; or
3. in respect of any additional or instalment premium, the date of it falling due,

whichever is the earliest.

If any premium (including any instalment premium) is not paid and accepted by **Us** in accordance with this clause, **We** shall provide written notice, within 7 (seven) days to **You**, in accordance with the 'Cancellation' clause.

Reasonable Care

1. **You** must take reasonable care to:
 - a. prevent accidents; and
 - b. maintain, and keep in good working order, premises, plant and equipment and everything used in connection with **Your Healthcare Services**; and
 - c. only employ competent employees; and
 - d. act in accordance with all statutory obligations, regulations and requirements of regulatory authorities.
2. **You** must in the event of any **Defect** or danger becoming apparent either:
 - a. make good or remedy any such **Defect** or danger; or
 - b. take such additional precautions as the circumstances require to avoid and/or mitigate the effects of such **Defect** or danger.

Regulatory Body

You must be registered with an applicable Regulatory Body throughout the **Period of Insurance** and any of **Your Employees** whose role obliges them to hold an appropriate licence must hold an appropriate licence and be registered with the appropriate body.

Subrogation and Recovery Proceedings

1. **You** shall provide such assistance as **We** may reasonably require in subrogation and/or recovery **Proceedings** and **You** shall take all steps necessary to preserve **Our** rights of subrogation and/or recovery and in particular **You** and/or **Your Employees** shall not enter into any arrangement or agreement contractual or otherwise with any party limiting or restricting in any way any of **Our** rights of subrogation and/or recovery;
2. **We** shall be subrogated to said rights of recovery of **You** and/or **Your Employees** against any party, whether before or after any indemnity is given under this **Policy**;

with the sole proviso that:

3. **We** shall not exercise rights of subrogation and/or recovery under Insuring Clause A – Medical Professional Liability or Insuring Clause B - Professional Indemnity (Financial Loss), against **Your Employees** unless the loss or **Claim** in respect of which indemnity is provided under this **Policy** was caused or contributed to by any fraudulent, dishonest or malicious act or omission by **Your Employee** or **Your Employees** against whom rights of subrogation or recovery are pursued.

Third Party Rights

Unless expressly stated, nothing in this **Policy** is intended to confer a directly enforceable benefit on any third party, whether pursuant to the Contracts (Rights of Third Parties) Act 1999, or otherwise. However, this will not affect rights enforceable under the Third Parties (Rights against Insurers) Act 2010 or the Ireland Law Reform (Contracts) Bill 2024

Transfer of Interest

Assignment of interest under this **Policy** shall not bind **Us** unless prior written consent is obtained from **Us**.

POLICY DEFINITIONS

Except for headings and unless expressed to the contrary, words, terms and phrases that are printed in bold shall have the meanings set out below.

Where any provision of this **Policy** contains specific defined words, terms and phrases, they apply to that particular provision only and must be read in conjunction with the following Policy Definitions, unless otherwise stated.

Abuse or Molestation

means

1. any deliberate or reckless act of hurting or injuring mentally or physically by maltreatment or ill-use;
2. any actual or alleged sexual crime or sexual misconduct by **You** or **Your Employees**;
3. repeated or continuing contemptuous, coarse, or insulting words or behaviours.

Additional Insured

means a company which has the main purpose of facilitating the financial or tax affairs of the individual **Registered Medical Practitioner** named in the **Schedule** of this **Policy** in respect of their medical, clinical or therapeutic services, and which is specifically named as an **Additional Insured** in the **Policy Schedule**.

Batch

means all **Products** produced within a single manufacturing cycle and specifically marked with a date, distinctive combination of letters, numbers or symbols, or any combination of the foregoing from which it can be determined that an individual item of the **Products** was produced during that cycle.

Bodily Injury

means death, injury, disease and any recognised psychiatric illness.

Bio Science Product

means any virus, therapeutic serum, toxin, anti-toxin or analogous product that is recognised in the British National Formulary, the official British Pharmacopoeia the official British Homeopathic Pharmacopoeia or any supplement to these documents or the equivalent in any other jurisdiction;

1. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans and which affects the structure or functioning of the human body; or
2. as a component of any **Products** described above;

but shall not include any **Pharmaceutical Drug**, **Medical Device** or food.

Circumstances

means any circumstances of which **You** become aware, or should reasonably have become aware, that may reasonably be expected to give rise to a **Claim**.

Claim

means any:

1. written or verbal demand made of **You**; and/or
2. assertion of any right against **You** including but not limited to any **Proceedings**, including any counter-claim; and/or
3. invitation to **You** and/or **Your Employees** to enter into alternative dispute resolution, alleging any **Occurrence**, negligent act, error or omission or loss or physical destruction, damage, loss or mislaying of any **Document** that may give rise to an entitlement to **Damages**.

Clinical Trials

means an organised study or test undertaken that uses human **Research Subjects** to establish the effectiveness, bioequivalence or safety of a **Pharmaceutical Drug**, **Bio Science Product** and/or **Medical Device**, under proper conditions of use and shall include any pre-trial assessment.

Computer System

means any computer, hardware, software, communications system, electronic device (including, but not limited to, smart phone, laptop, tablet, wearable device), server, cloud or microcontroller including any similar system or any configuration of the aforementioned and including any associated input, output, data storage device, networking equipment or back up facility, owned or operated by **You** or any other party.

Costs

means **Your** defence costs and expenses, including appeal costs, in respect of any **Claim** against **You** and/or **Your Employees** to which an indemnity in this **Policy** applies.

Costs shall not include any of **Your** and/or **Your Employees'** fees, salaries or expenses.

Criminal Prosecution Defence Costs

means:

1. defence costs in respect of any criminal proceedings or appeal in any criminal proceedings brought against **You** and/or **Your Employees**; and/or
 2. defence costs for proceedings in any Court of summary jurisdiction or other local equivalent.
-

Cyber Incident

means:

1. any error or omission or series of related errors or omissions involving access to, processing of, use of or operation of any **Computer System**; or
 2. any partial or total unavailability or failure or series of related partial or total unavailability or failures to access, process, use or operate any **Computer System**.
-

Cyber Act

means an unauthorised, malicious or criminal act or series of related unauthorised, malicious or criminal acts, regardless of time and place, or the threat or hoax thereof involving access to, processing of, use of or operation of any **Computer System**.

Damages

means compensatory monetary amounts and/or in respect of claimant's costs and expenses in judgments, arbitration awards and/or settlements, always provided any such settlement is made with **Our** prior written consent and is in relation to a **Claim** for which **You** or **Your Employees** would otherwise be legally liable to pay, in respect of any matter that may be the subject of indemnity under this **Policy**. Always provided that **Damages** shall not mean nor include:

1. fines whether civil or criminal, sanctions penalties or forfeiture, set-off, off set, irrespective of whether due to statute regulation or court rule;
 2. the multiplied portion of multiplied awards;
 3. injunctive or declaratory relief;
 4. any other punitive or exemplary amounts regardless of whether they arise under civil law, criminal law or under the jurisdiction of any professional body or regulatory authority;
 5. any amount that is not insurable under any applicable law;
-

Data

means information, facts, concepts, code or any other information of any kind that is recorded or transmitted in a form to be used, accessed, processed, transmitted or stored by a **Computer System**.

Data Breach

means:

1. the theft, loss, access to, acquisition of, or unauthorized or unlawful use or disclosure of any person's or organization's confidential or personal information, including patents, trade secrets, processing methods, customer lists, financial information, credit or payment card information, health information, biometric data or any other type of non-public information involving access to, processing of, use of or operation of any Computer System; or
 2. the violation of any statute, regulation, common-law, or any other law including **Data Protection Laws** regulating or protecting access to collection, use or disclosure of, or failure to protect any non-public confidential or personal information in the form of **Electronic Data**.
-

Data Protection Laws

means the Data Protection Acts 1984, 1998, 2018, the Privacy and Electronic Communications Regulations 2003, the General Data Protection Regulation and the UK General Data Protection Regulation or any amendments thereto and any equivalent law in any jurisdiction.

Defect

means an actual harmful condition which:

1. is not intended by **You** and/or **Your Employees**; and/or which
 2. a reasonable person in the circumstances of **You** and/or **Your Employees** would not expect; and/or
 3. arises out of **Your** and/or **Your Employees'** conduct or the conduct of a person or organisation acting on **Your** behalf; and/or
 4. causes or presents a substantial likelihood of causing **Bodily Injury** or **Property Damage**.
-

Document

means documents of any kind including but not limited to forms, deeds, wills, agreements, maps, plans, books, letters, policies and certificates, whether written, printed or reproduced by any method, including computer records and electronic material, but excluding stamps, bearer bonds or coupons, money or other negotiable instruments.

Electronic Data

means facts, concepts and information converted to a form useable for communications, interpretation or processing by electronic and electromechanical data processing or **Computer Systems** and includes programs, software and other coded instructions for the processing and manipulation of data or the direction and manipulation of such equipment.

Excess

means the amounts specified as such for each Insuring Clause in the **Schedule** which **You** have agreed to retain as self-insured amounts, which amounts do not erode the **Limit of Indemnity** and which amounts shall be applied and paid first by **You** in relation to any **Costs** and/or **Damages** incurred in respect of any **Claim**.

Good Samaritan Act

means treatment or care administered at the scene or in the immediate aftermath of a medical emergency, accident or disaster, by **You** whether alone or alongside professional emergency response personnel if **You** are present or available to assist either by chance or in response to an SOS call following a disaster, and where **You** were not being remunerated or rewarded for the treatment or care.

Healthcare Services

means services performed by **You** and/or **Your Employees** or on **Your** behalf to care for, treat or assist patients and/or **Research Subjects** and shall include:

1. The provision of training, medication or appliances, food and beverages in connection with such services, and the post mortem handling of human bodies; and
2. **You** appearing as an expert witness and/or providing formal medical reports or opinion or advice and/or **Medical Committee Services**; and
3. Administrative and secretarial tasks needed to allow for the provision of these services.

Interrelated Claims

means any one **Claim** or series of **Claims** or multiple **Claims** arising out of an **Occurrence** or series of **Occurrences** consequent upon or directly or indirectly attributable to one source or original cause or common underlying causes, whether or not occurring at the same time or location. For these purposes an underlying source or original cause shall include but not be limited to any one **Batch**.

Libel and Slander

means one or more of the following, committed in the course of advertising **Your Products** or advertising **Your Healthcare Services**:

1. oral or written publication of material that defames a person or organisation or disparages a person's organisation, goods, product or services;
2. oral or written publication of material that breaches a person's right to privacy;
3. misappropriation of advertising ideas or styles of doing business;
4. infringements of copyrighted advertising materials, titles, slogans or trademarks.

Limit of Indemnity

means the aggregate limit of indemnity and/or the limit applicable to any relevant operative Insuring Clause and/or any sub limit as shown in the **Schedule**.

Medical Committee Services

You sitting on any medical advisory review board or committee for the furtherance of training, or evaluation of professional qualifications or of clinical performance of healthcare professionals and/or secretarial and administrative tasks required to provide those services or to comply with professional obligations, whether carried out by **You** or **Your Employees**.

Medical Device

means:

1. an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, component, part or accessory; and
2. which is subject to regulatory approval within the **Territorial Limits** applicable to the relevant Insuring Clause; and
3. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans and which affects the structure or functioning of the human body,

but shall not include any **Pharmaceutical Drug** or **Bio Science Product**.

Occurrence

means any loss, event, incident or accident, or series of losses, events, incidents or accidents arising out of, consequent upon or directly or indirectly attributable to one source or original cause or common underlying causes, whether or not occurring at the same time or location.

Territorial Limits**Opioids**

means a class of pain relieving drugs that act by binding to opioid receptors.

Period of Insurance

means the period specified in the **Schedule** and/or such other period agreed by **Us**.

Pharmaceutical Drug

means a synthetic or natural chemical recognised in the British National Formulary, the official British Pharmacopoeia, the official British Homeopathic Pharmacopoeia or any supplement to these documents or the equivalent in any other jurisdiction:

1. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans and which affects the structure or functioning of the human body; and/or
2. as a component of any **Product**.

Policy

means and includes:

1. the **Schedule**, Insuring Clauses indicated as operative in the **Schedule**, Policy Extensions, Policy Exclusions, Policy Conditions, and Policy Definitions, and all notices and other documents attaching;
2. all endorsements incorporated in and issued for incorporation in this document;

and all of which shall be read together and constitute the contract of insurance.

Pollution

means the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape, whether permanent or transitory, of any solid, liquid, gaseous or thermal irritant or contaminant, including smoke, vapour, soot, fibres, fumes, acids, alkalis, chemicals, any other hazardous materials and waste. Waste includes material to be recycled, reconditioned or reclaimed.

Prior Acts Period

means: The period of time in which **You** were indemnified on a claims-made basis or were a member of a Medical Defence Organisation. Should a claim or regulatory referral arise for activities prior to inception of this **Policy** or if applicable, any retroactive date of a previous policy, and the previous insurer or Medical Defence Organisation decline coverage, **We** will take over the **Claim** and subrogate against the previous insurer or Medical Defence Organisation on **Your** behalf.

Proceedings

means

1. civil, criminal or regulatory proceedings in any jurisdiction brought against **You** or **Your Employees**; and/or
2. proceedings brought by **Us** in the exercise of **Our** rights of recovery and/or subrogation.

Products

means any products or goods including their packaging, containers, labelling and instructions provided in connection with the products or goods, manufactured, sold, supplied, distributed, processed, installed, serviced, repaired, altered, treated or renovated by **You** or **Your Employees** in connection with **Your** business as a **Registered Medical Practitioner**.

Always provided that those products or goods which are the subject of a continuing **Clinical Trial** shall not be included within the said **Product** defined term.

Property

means property which is both material and tangible.

Property Damage

means the physical loss of or physical damage to **Property**.

Registered Medical Practitioner

means a medical practitioner registered with the General Medical Council or Irish Medical Council

Regulatory Hearing and Inquest Costs

means **Costs** of any non-criminal investigation into **Your** professional competence or conduct, including any such investigation instigated by:

1. a regulatory body (including the Care Quality Commission); or
2. a coroner or Coroners Court (in England, Wales and Republic of Ireland) or procurator (in Scotland) or Fatal Accident Inquiry or any local equivalent.

Territorial Limits**Reporting Period**

means: The time after the end of a **Prior Acts Period** which is allowed for reporting **Claims** which occurred during the **Prior Acts Period**. In accordance with the rules, rates and rating plans in effect for the company, the last **Reporting Period** shall be "unlimited" meaning without a termination date.

Research Subject

means any person participating or taking part in a **Clinical Trial** or any pre-trial assessment, their dependants, heirs, estate or legal representatives.

Retroactive Date

means the relevant date specified in the **Schedule**.

Schedule

means the schedule in force and forming part of this **Policy**.

Territorial Limits

means the territories to which cover is limited as stated in the **Schedule**.

Terrorism

means any act including, but not limited to, the use of force or violence or the threat thereof, by any person or group of persons (whether acting alone or on behalf of or in connection with any organisation or government) committed for political, religious, ideological or similar purpose, including the intention to overthrow or influence any government, whether or not legally constituted, or to put the public or any section of the public in fear.

United Kingdom / UK

means England, Scotland, Wales, Northern Ireland, the Channel Islands and the Isle of Man.

Voluntary Act

means any treatment or care administered by **You** in a voluntary capacity having volunteered to attend at an organisation or event in order to provide care to, treat or assist other persons attending the organisation or event where **You** were not being remunerated for otherwise rewarded for that care, treatment or assistance.

War

means war (whether war be declared or not), invasion, acts of foreign enemies, hostilities or warlike operations, civil war, mutiny, revolution, rebellion, insurrection, uprising, military or usurped power or confiscation by order of any public authority or government de jure or de facto or martial law but not including **Terrorism**.

We or Us or Our

means the insurer named in the **Schedule** of this **Policy**.

You or Your

means the individual **Practitioner** named in the **Schedule** of this **Policy** and also includes the **Additional Insured**.

Your Employees

means any person whose work or service is directed and controlled by **You** under a contract of employment or contract for service while acting in the course of that contract of employment or service and shall include;

1. a worker hired by or seconded to **You**; and/or
2. a volunteer, including a person on a course of study with **You** while engaged in working for **You** in connection with **Your** business and/or
3. any agency or bank staff working for **You**; and/or
4. any person on a course of study with **You**; and/or
5. any person engaged by **You** in connection with a work experience or training scheme; and/or
6. any natural persons whose role it is to provide medical secretarial and/or medical administration and/or clinical practice management services to **You**, whether or not that person is directly employed by **You**.

Your Employees shall not include any **Registered Medical Practitioner**.

The Data Protection Notice does not form part of the **Policy**

The Data Protection Notice may be updated, amended, and/or replaced from time to time. The latest version of the Data Protection Notice will be made available on the website of the **Insurer**.

DATA PROTECTION NOTICE

Introduction: This is a concise version of the Insurer's Data Protection Notice. The full version is available here: www.cnahardy.com/privacy Personal Data means data which by itself or with other data available can be used to identify an individual. The Insurer shall process Personal Data that it obtains in connection with this Policy in accordance with its Data Protection Notice, or where applicable, the Data Protection Notice of its local branch operations in Europe (available at www.cnahardy.com) and as summarised herein.

See www.cnahardy.com/privacy for our legal entity and branch office names and registered contact details. You must view this, including if the Insurers' company or branch who is processing your Personal Data is outside the UK (since local country requirements apply there). Please show it to all individuals whose Personal Data is processed by us and obtain their consents (where relevant). UK only: You can contact us at: DataProtectionOfficer@CNAHardy.com or write to our Data Protection Officer, General Counsel Department, 13th Floor, 20 Fenchurch Street, London, EC3M 3BY. For our office locations and contact details outside the UK: www.cnahardy.com/privacy If in the Policy documentation (as relevant) certain Personal Data is missing or if this proves to be inaccurate, we may not be able to administer the Policy.

The Insurer ("we", "us", "it") may process Personal Data in order to arrange the Insured's insurance cover (including renewals and Claims), to comply with a legal requirement, to administer accounts, to provide customer service, to perform credit checks, to engage in fraud prevention and market our products and services. In addition, we may use it for the purposes more particularly described below.

Categories of Personal Data we collect (some of this is collected indirectly e.g. from brokers and intermediaries): We may collect your full name, home address, date of birth, other identification details such as the proof of identity and proof of address documentation; your contact information, including your work related email address and telephone number, your work address, and (if you are a director, partner or other legal or beneficial owner of the Insured) your home address; criminal conviction or offence details including any actual or suspected fraud, money laundering or other crimes.

The legal basis and purposes of use:

The purposes of use include arranging the Insured's insurance cover (including communications about the Policy, for renewals and for administration/processing of Claims and of the Policy), for management and audit of our business operations including accounting, to verify identity/ies such as sole traders, directors, officers, partners and other legal or beneficial owners of the Insured, to perform fraud prevention and anti-money laundering checks, for establishment and defence of legal rights, to comply with legal or regulatory requirements, for other activities relating to the prevention, detection and investigation of crime, to administer accounts and provide customer service, for market research and to market our products and services and those of our Group of companies.

The legal basis includes processing necessary to perform our obligations under the Policy (if you are the individual entering into that Policy with us – e.g. sole traders); processing necessary for our legitimate interests and those of our other companies and branches, including for our good governance obligations, monitoring emails and other communications (see below) and to administer the Policy; and processing necessary for compliance with our legal obligations or those of the relevant company or branch within CNA Hardy or to establish or defend legal claims or rights.

We may also process Personal Data based on your consent. For instance, if you request us to share it with other people or organisations; when we process special categories of personal data about you at your request (this is defined in the full version) and to send marketing communications where we have asked for consent to do so. You are free at any time to withdraw your consent. The consequence might be that our ability to administer the Policy is affected or that we cannot do certain things for you.

Data sharing: In order to arrange the **Insured's** insurance cover, or process any **Claims**, the **Insurer** may disclose Personal Data to other companies within its Group, its insurance partners and other third parties who act for the **Insurer** for further processing, brokers, intermediaries, agents, underwriters, loss adjusters, our legal and other professional advisers, government regulators and the Ombudsman, and other third parties and service providers who help us and our Group to operate our business; with regulatory authorities, courts and governmental agencies to comply with legal orders, legal or regulatory requirements and government requests; in the context of a sale of all or part of our group of companies or transfer of business assets; with Fraud Prevention Agencies and the Association of British Insurers (UK only) or equivalent industry bodies in your country. In some instances, it may be necessary to transfer Personal Data between the **Insurer's** European and international offices. This may include Personal Data being disclosed to legal or regulatory bodies in order to comply with diverse legal regulations, including those imposed on the **Insurer's** parent company based in the United States. The **Insurer** shall endeavour to ensure that any such data processed or disclosed is appropriately protected by technical and operational security measures and contractual measures where necessary.

International transfers: Your Personal Data will be transferred outside the UK and the European Economic Area, including to companies in our Group who are in the US. Some countries have applicable laws giving adequate protections for Personal Data. In others (including the US) steps will be necessary to ensure appropriate safeguards, such as contractual obligations of adequacy or requiring the recipient to subscribe or be certified with an 'international framework' of protection. U.S. defence and security authorities may gain access to your Personal Data.

Criteria used to determine the retention period: We will apply this criteria: retention in case of queries (e.g. in case of queries from you or the Insured); retention in case of claims (e.g. for the period in which the Insured might legally bring claims against us); and retention in accordance with legal and regulatory requirements (e.g. after the Policy has come to an end).

Identity verification and Fraud Prevention Checks: Your Personal Data will be shared with fraud prevention agencies who will use it to prevent fraud and money-laundering and to verify your identity. If fraud is detected, you could be refused certain services, finance or employment in future. It will be used to enable law enforcement agencies to access and use your Personal

Data to detect, investigate and prevent crime. Fraud prevention agencies can hold your Personal Data for different periods of time, depending on how that data is being used. You can contact them for more information. If you are considered to pose a fraud or money laundering risk, they will keep it for up to 6 (six) years.

Data Anonymisation: Your Personal Data may be converted into statistical or aggregated data which cannot be used to identify you, then used to produce statistical research and reports. This aggregated data may be shared and used in all the ways described above.

Direct Marketing: We will use your contact details to keep the Insured informed by post, telephone or e-mail of our additional products or services and developments in the insurance sector generally, including after the Policy has lapsed. You can change your preferences or unsubscribe at any time – details will be in the message – alternatively email or write to us (see above).

Your rights under applicable data protection law: Your rights may include the following (noting that these rights do not apply in all circumstances and that data portability is only relevant from May 2018): the right to be informed about our processing of your Personal Data; the right to have your Personal Data corrected if it is inaccurate and to have incomplete personal data completed; the right to object to processing of your Personal Data; the right to restrict processing of your Personal Data; the right to have your Personal Data erased (the “*right to be forgotten*”); the right to request access to your Personal Data and information about how we process it; the right to move, copy or transfer your Personal Data (“*data portability*”); and rights in relation to automated decision making including profiling. You have the right to complain to the supervisory authority in your country who enforces data protection laws. In the UK see: <https://ico.org.uk/> For supervisory authorities in other countries see www.cnahardy.com/privacy.

Insurance market fraud monitoring system (UK only): We may submit your Personal Data into an insurance industry wide fraud monitoring system. This is an industry wide fraud database administered by a third party and used by other members of the insurance industry in the UK. Other members of the industry will see it if any fraud risk is identified.

Questions about the Insurer's data protection practices should be directed to the Insurer at the details set out at the beginning of the Data Privacy Notice]

COMPLAINT PROCEDURE

It is our intention to provide you with a first class service. However, there may be occasions when you feel that this objective has not been achieved. Please direct any enquiry or complaint as follows:

1. If you have a complaint about the service you have received from your insurance advisor, please contact them directly.
2. If you have a complaint relating to a **Claim** handled by CNA Insurance Company Limited, or a **Claim** handling agent appointed by CNA Insurance Company Limited, please contact The Claim Director at the 'Claims notification' address set out in the **Schedule** to the Policy.
3. If you have a complaint relating to a **Claim** handled by Hardy (Underwriting Agencies) Limited, or a **Claim** handling agent appointed by Hardy (Underwriting Agencies) Limited, please contact The Claim Director at the 'Claims notification' address set out in the **Schedule** to the **Policy**.
4. If you have a complaint about any other aspect of the service you have received from CNA Insurance Company Limited or Hardy (Underwriting Agencies) Limited please contact the Head of Legal & Compliance Services at the '**Insurer's** address' set out in the **Schedule** to the **Policy**.

Please provide the following information with your complaint:

1. Your **Policy** number and/or **Claim** reference number (if applicable);
2. Your full name, address and telephone number;
3. Details of any previous correspondence relating to the matter;
4. The name of any claims handling organisation with whom you have been dealing, and their reference number (if applicable); and
5. State the nature and provide full details of your complaint.

You shall receive an acknowledgement within 5 (five) working days of receipt of your complaint, together with a detailed timetable of the actions we shall take to investigate / handle your complaint. In the event the matter is still not resolved to your satisfaction and you wish to pursue matters further, you may be able to refer the matter to The Financial Ombudsman Service (FOS).

The FOS shall become involved if you are an eligible complainant, as defined by the rules of the Financial Conduct Authority.

Eligible complainants are a:

1. private policyholder, or
2. micro enterprise, (that is an enterprise which employs fewer than 10 persons and has a turnover or annual balance sheet that does not exceed EUR 2 million), or
3. charity with a turnover of less than GBP 6.5 million, or
4. trustee of a trust with an asset value of less than GBP 5 million.

The FOS shall only consider a complaint if the **Insured** is an eligible complainant and if:

1. the **Insurer** has been given an opportunity to deal with the matter; and
2. the **Insurer** has sent you a final response letter and you have referred your complaint to the FOS within 6 (six) months of the **Insurer's** final response letter, or
3. the **Insurer** has not responded to your complaint with a decision within 8 (eight) weeks.

The existence of this Complaint Procedure does not affect any right of legal action you may have against the **Insurer**.

Financial Ombudsman Service Contact Details:

The Financial Ombudsman Service

Exchange Tower

London E14 9SR

Telephone: 0800 023 4567 (from a fixed line)
0300 123 9 123 (from a mobile telephone)
+44 20 7964 0500 (from outside of the UK)

Email: complaint.info@financial-ombudsman.org.uk

Website: www.financial-ombudsman.org.uk

Financial Services Compensation Scheme

CNA Insurance Company Limited and Hardy (Underwriting Agencies) Limited are covered by the Financial Services Compensation Scheme. The **Insured** may be entitled to compensation from the Scheme if the **Insurer** is unable to meet its obligations under this contract.

Entitlement to compensation under the Scheme depends on the type of business and circumstances of the **Claim**. Further information about compensation scheme arrangements is available from the Financial Services Compensation Scheme 10th Floor, Beaufort House, 15 St Botolph Street, London EC3A 7QU or from their website (www.fscs.org.uk).

Important contact details

You will discover several contact details referenced throughout this **Policy**. **You** should read the relevant section of the **Policy** alongside these details.

As above, any questions regarding the cover provided under this **Policy** please refer to **Your** broker or agent.