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| **Unimutual Limited** | **ABN 45 106 564 372** | **AFS Licence No 241142** |

**CLINICAL TRIALS DATA COLLECTION FORM**

**Protection Period: 1 November 2018 - 31 October 2019**

**This is not an offer of membership or of discretionary protection by Unimutual Limited**

Any offer of membership and the contribution payable for the Protection Period will be based on the information submitted by the applicant in this data collection form. By completing and lodging this form the applicant is declaring that the information at the time of lodgment is correct to the best of the applicant's knowledge and belief and that it is not deficient in any material respect.

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| **Applicant's Details** |
|  |  |
| Applicant’s Full Name: |  |
|  |  |
| Name and Position of Applicants Representative: |  |
|  |  |
| Applicants Postal Address: |  |
|  |  |
| Applicants ABN: |  |
|  |  |
| Telephone: |  |
|  |  |
| Email: |  |
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| **Declaration** |
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| On behalf of the applicant and each affiliate nominated by it, I declare and warrant that, after enquiry, all statements and particulars contained in this Data Collection Form and the supporting material accompanying this form are true and that no information has been withheld that may increase the risk to Unimutual, influence its decisions to consider an application for membership or the level of contribution applicable. I acknowledge on behalf of the applicant that if the information in this form or the supporting material changes in any way, Unimutual must be advised of the changes as soon as practicable. |
| Form Completed by: |  |
|  |  |
| Position: |  |
|  |  |
| Signature: |  |
|  |  |
| Date: |  |
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**ABOUT THIS DATA COLLECTION FORM**

In addition to the four core protections offered to members, members of Unimutual may apply for protection for Clinical Trials subject to statutory requirements in force at the relevant time.

## Clinical Trials Protection

CLINICAL TRIAL DEFINITION

a) Any human trial or heath volunteer study which complies with the statutory requirements or guidelines of the relevant authority, department or public or registered private body in the country in which the trial or study takes place or

b) A study that has to be approved by the Members Human Ethical Committee.

NOTE: Only CTN and CTX trials which are current or completed during the Protection Period or due to commence in the next Protection Period are required to be included in the listing of Clinical Trials.

Only those trials that fall under the Clinical Trial definition fall under the Clinical Trials Protection. If the trial does not fall under the definition then either the General and Products Liability, Professional Liability or Malpractice Protection will apply if applicable

**Please note:**

**1. Clinical Trials Protection does not automatically apply to the entities nominated by the Applicant as Affiliates for the purposes of the four core protections offered by Unimutual.**

**If the Applicant wishes to extend the Clinical Trials Protection to include any entity other than the Applicant and the persons specified as “Protected Person”, the Applicant must specify the entity by listing it in answer to Question 1.2 of this Data Collection Form**

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| SECTION 1 | GENERAL INFORMATION |

The information requested in this data collection form requires information to be provided about the applicant as well as any affiliate nominated by the applicant.

Where the answer required is YES or NO please click on the box of the appropriate answer and check the box. Where the question requests specific information please provide the information in the format required.

**APPLICANT**

Only universities or other educational institutions or research institutions or entities associated with education or research or with education or research institutions that have more than 20 employees are eligible for membership of Unimutual.

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| **1.1** | **Has the Applicant completed the data collection form for the four core protections offered by Unimutual?** | **YES** **[ ]**  | **NO** **[ ]**  |

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|  | If **NO**, then the applicant should discuss the application with Unimutual beforecompleting the rest of this data collection form. If **YES**, please complete the remainder of this document. |

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| **1.2** | **Does the Applicant wish to have its Clinical Trails protection extended to any other entities?** | **YES [ ]**  | **NO [ ]**  |

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|  | If **YES**, please complete table below. |

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| **Name of Affiliate** | **Description of Activities** | **Applicant's ownership of Affiliate (%)** |
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**Note:** A member of Unimutual is able to lodge a claim for protection on its own behalf or on behalf of an affiliate named in the Protection Schedule

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| SECTION 2 | PROTECTION LIMITS AND RETENTIONS |

**LIMIT OF PROTECTION**

The Clinical Trials Protection are subject to a combined Limit of Protection for each and every claim as well as a limit in the aggregate as specified in the Member's Schedule for this Protection.

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| **2.1** | **Please nominate the Limit of Protection for Malpractice Protection requested by the Applicant for the Protection Period** |

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|  | $      each and every claim but limited to $       in the aggregate for the Protection Period |

**NOMINATED RETENTION**

The Retention is the amount that the member must contribute to each successful claim for protection. The Retention will become payable by the Member when Unimutual makes any payment to a third party or incurs legal or investigation fees in defending or investigating a claim instigated by a third party. For the purpose of applying the Retention, all Bodily Injury resulting from or alleged to have resulted from the same Clinical Trial will be considered by Unimutual as resulting from one Occurrence

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| **2.2** | **Please nominate the Clinical Trial Retention requested by the Applicant for each and every claim** | **$** **(inclusive of defence costs) for each and every claim** |

**CLAIMS HISTORY**

For the purposes of this Section, a claim is any written or verbal notice of demand for damages or compensation made against the Member or Affiliate by a Research Subject involved in any Clinical Trial undertaken by the Member of Affiliate

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| **2.3** | **Does the Member or Affiliate have any knowledge of any claim being made against the Member or Affiliate by any Research Subjects involved in any Clinical Trials undertaken by the Member or Affiliate during the last 10 years?** | **YES [ ]**  | **NO [ ]**  |

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|  | If **YES**, please provide details below |

Note: In the case of no claims being made please record "NONE"

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| SECTION 3 | DETAILS OF CLINICAL TRIALS |

The following are required to be included in the listing of Clinical Trials provided:

* all **CTN and CTX trials** which are current or completed during the Protection Period or due to commence in the next Protection Period
* all Trials that are a **Multi-Centre** trial/study
* any Trial/study where you are **collaborating with any other Australian University or Research centre**
* any trial/study where **you are the Sponsor** and **involving any other Australian University or Research Centre**, or the **Sponsor is another Australian University or Research Centre**

**Please provide your excel spreadsheet with the following information:**

|  |  |  |
| --- | --- | --- |
| **Title** | **Question** |  |
| 1. Your Reference Number |  |  |
| 2. School/Department | School/Department conducting the trial. |  |
| 3. (a) Clinical Trial Title | Provide the trial name |  |
| 3. (b) Trial Description | Provide a brief description of the trial |  |
| 4. CTN or CTX | Is the trial a CTN or CTX trial? |  |
| 5. (a) Role of the Member | What is the Role of the Member in this Clinical Trial? |  |
| 5. (b) Role of the Member Details | If the Member is not the Principal Investigator what role do they hold? |  |
| 6. Ethics Approval (By whom) | Institution that granted Ethics Approval |  |
| 7. Sponsor | Provide the name of Sponsor (if not You) and their Clinical Trial insurance policy limit. |  |
| 8. Sponsor Indemnity | Is an indemnity provided by the sponsor? |  |
| 9. Principal Investigator | Is the Member the Principal Investigator? |  |
| 10 (a) Principal Investigator Details | Name of Principal Investigator and position |  |
| 10 (b) Principal Investigator relationship to Member | What is the Principal Investigator's relationship to the Member? |  |
| 11. Start Date | Start Date of Trial |  |
| 12. End Date | Expected end date of trial |  |
| 13. Granting Body | Granting body for non-sponsored trial. If applicable. |  |
| 14. Invasive nature of trial | Provide details of any invasive procedures to be used during the trial. eg taking of blood samples, tissue sampling, surgical procedures, ingestion of any substances, application of creams, ointments etc |  |
| 15. Adverse Events for this Trial (if applicable) |  |  |
| 16. Name of Drug |  |  |
| 17. Dosage of Drug |  |  |
| 18. Target Participant Number | Number of participants anticipated to be involved in the trial during the next twelve months (if your role is sponsor or Principal investigator - all sites). |  |
| 19. Target Participants for whole trial period | Number of participants anticipated to be involved in the whole trial. |  |
| 20. Is this Trial a Multi-Centre trial/study? |  |  |
| 21. (a) Are you collaborating with any other Australian University or research centre? |  |  |
| 21. (b) Details of collaborating institution/s | Please provide details if you are the sponsor and involving any other Australian university or research centre; or the sponsor is another Australian university or research centre: |  |
| 22. (a) Number of Sites | Total number of sites |  |
| 22. (b) Site Locations | Location of trial sites where the Member will be conducting the trial (State/s if within Australia or Country/s if overseas) |  |
| 23. Comments | Provide and additional comments (if applicable) |  |