# **Clinical Trial Research Agreement and Indemnity Form Submission Checklist**

**Trial Details**

**Submission Instructions:** Include the following detail in the submission email when providing clinical trial research agreements and documents to confirm clinical trial sponsor responsibilities and attach word versions of documents for review and signature.

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| **HREC Approval Number** |  |
| **RG Reference Number** |  |
| **Approving HREC** |  |
| **Trial Title:**  |  |
| **Coordinating Principal Investigator** |  |
| **Trial Site**  |  |
| **Trial Site Investigator** |  |
| **Clinical Trial Protocol Version Number and Date** |  |
| **Trial Sponsor** | UNSW |
| **Trial Type** | [ ]  Clinical Trial – Investigational Medical Device[ ]  Clinical Trial – Investigational Medical Product [ ]  Clinical Trial – Health Intervention [ ]  N/A – Not a Clinical Trial |

**Coordinating Principal Investigator Approval**

**Submission Instructions:** The following must be attached to the submission email for all documents submitted for signature.

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| Evidence of email approval from the Coordinating Principal Investigator (CPI) must be provided. The CPI must include the following in their approval email:1. I approve the CTRA, and details provided in the document.
2. Submitting the CTRAs has been delegated to the person submitting the documents for signature by email.
3. The CTRA and Indemnity forms were reviewed and approved by them before submission.
4. There is sufficient funding to cover the cost of the payments listed in schedule two until the trial is completed at the site.
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**Medicines Australia Clinical Trial Research Agreement**

* The following items must be completed when drafting CTRAs for signature. Please note that this form must not be submitted with the draft CTRAs.
* Documents must be provided in word format for signing.

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| **International Clinical Trial Research Agreements** * The research team must contact UNSW Legal to establish which agreement template should be used for clinical trials conducted overseas legaloffice@unsw.edu.au
 | [ ]  Completed[ ]  N/A |
| **UNSW Sponsored Clinical Trials Conducted at Australian Sites*** Download the current Medicines Australia Clinical Trial Research Agreement – Collaborative or Cooperative Research Group (CRG) Studies Template from the Medicines Australia website (<https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/>).
 | [ ]  Completed |
| Page 1: Remove the information in the greyscale box. | [ ]  Completed |
| Page 1, institution: Insert the name, address and ABN of the institution responsible for the site where the trial will be conducted.  |  |
| Page 1, CRG Name: Insert, ", University of New South Wales, a body corporate established under the University of New South Wales Act 1989 (NSW)If the Kirby Institute is conducting the trial, The following wording is to be used "*University of New South Wales, a body corporate established under the University of New South Wales Act 1989 (NSW), as represented by The Kirby Institute for Infection and Immunity in Society".* | [ ]  Completed |
| Page 1, address: Insert, "UNSW Research Ethics & Compliance Support, Level 3Rupert Myers Building South Wing (M15), UNSW Kensington CampusNSW 2052" in this section.  | [ ]  Completed |
| Page 1, ABN: Insert "57 195 873 179" in this section. | [ ]  Completed |
| Page 1, contact for notices: insert clinical trial coordinator or coordinating principal investigator details. | [ ]  Completed |
| Page 1, fax for notices:insert fax number if applicable or mark as N/A. | [ ]  Completed |
| Page 1, email for notices: insert an email address. | [ ]  Completed |
| Page 1, phone number: insert clinical trial coordinators or coordinating principal investigators' details.  | [ ]  Completed |
| Page 1, study name: Insert the study title and ensure that this is consistent with the HREC-approved title and the clinical trial protocol title.  | [ ]  Completed |
| Page 1, protocol number: Insert the HREC approval and the trial protocol number or acronym. | [ ]  Completed |
| Footer protocol number: Insert the HREC approval number and trial acronym. | [ ]  Completed |
| Footer, site name: Insert the site name for the CTRA.  | [ ]  Completed |
| Pages 2 – 18: Do not make any changes to the text on these pages. If changes are required to these items, they must be reflected in schedule 4 of the CTRA.  | Changes made[ ]  Yes[ ]  No |
| Page 19, CRG, name: Add Dr Ted Rohr | [ ]  Completed |
| Page 19, CRG, position: Add Director of UNSW Research Ethics Compliance Support | [ ]  Completed |
| Page 19, Principal Investigator name: Add the principal investigator's title and name. | [ ]  Completed |
| Page 19, Principal Investigator, position: Add the principal investigator position. | [ ]  Completed |
| Page 20, study name: Insert the study title and ensure that this is consistent with the HREC-approved title and the clinical trial protocol title. | [ ]  Completed |
| Page 20, study sites: Insert the study sites that the CTRA will cover. | [ ]  Completed |
| Page 20, protocol number: Insert the HREC approval number and trial acronym.  | [ ]  Completed |
| Page 20, target number of participants: Insert the minimum and maximum number of participants to be recruited.  | [ ]  Completed |
| Page 20, recruitment period: Add the start and end dates for recruitment at the trial site.  | [ ]  Completed |
| Page 20, Principal Investigator Name: Add the title and name of the principal investigator and ensure these details are consistent with what is specified on page 19. | [ ]  Completed |
| Page 20, reviewing HREC: Insert the name of the reviewing HREC for the trial site. Ensure that the [external ethics approval process](https://research.unsw.edu.au/external-ethics-approval-ratification) has been completed for the initial HREC approval and any subsequent amendments. | [ ]  Completed |
| Page 20, equipment provided by the CRG: Add the details of any equipment, including devices to be provided for the site to conduct the trial following the clinical trial protocol.  | [ ]  Completed |
| Page 20, at the end of the study: Indicate what the site is required to do at the end and ensure that these align with clauses 7.5 and 7.6.  | [ ]  Completed |
| Page 20, software provided by the CRG: Add the details of any software provided for the site to conduct the trial following the clinical trial protocol. | [ ]  Completed |
| Page 20, investigational product: Insert the details of any investigational product that will be provided to the trial site to allow them to conduct the trial following the clinical trial protocol.  | [ ]  Completed |
| Page 21: Insert the details of all payments to the trial site. The following must also be completed:* An overall trial budget with a breakdown of site payments must also be developed and provided along with the first CTRA for the clinical trial or when the budget is amended.
* Payments must specify the number of times payments will be made for each item listed in this section throughout the trial start and finish dates.
* Instructions for the site to issue requests for payments and invoicing details must be included in this section.
 | [ ]  Completed |
| Page 22, Schedule 3: Insert the current HREC-approved clinical trial protocol. Ensure that the [external ethics approval process](https://research.unsw.edu.au/external-ethics-approval-ratification) has been completed if the clinical trial protocol has been amended and approved by the approving HREC.  | [ ]  Completed |
| Page 23, Schedule 4: All items listed in this section must be approved by UNSW Legal before CTRAs with these items can be signed. Please allow for additional processing time while UNSW Legal approval is obtained. RECS will submit all CTRAs with schedule 4 clauses to UNSW and copy in the Coordinating Principal Investigator and the research team.  |  |

**Medicines Australia Form of Indemnity**

* The following items must be completed when drafting the indemnity form for signature. Please note that this form must not be submitted with the draft indemnity form.
* Documents must be provided in word format for signing.

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| The [Medicines Australia](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/) Form of Indemnity - Standard template is used. | [ ]  Completed |
| Page 1, to the Indemnified Party: Insert the name, address and ABN of the institution responsible for the site where the trial will be conducted. | [ ]  Completed |
| Page 1, from the sponsor: University of New South Wales, a body corporate established under the University of New South Wales Act 1989 (NSW), ABN: 57 195 873 179, UNSW Kensington Campus, NSW 2052 | [ ]  Completed |
| Page 1, RE: Enter the HREC approval number or clinical trial protocol number, the study title and the product being used if applicable. | [ ]  Completed |
| Page 2, Sponsor Name: Insert Dr Ted Rohr | [ ]  Completed |
| Page 2, Sponsor Position, Director of UNSW Research Ethics Compliance Support. | [ ]  Completed |