**Clinical Trial Governance Application Form**

**University of Tasmania as trial sponsor**

This form is to be completed for all clinical trials when the University of Tasmania is acting as **sponsor only** (i.e. the trial is being conducted at a site elsewhere). A sponsor is defined as the organisation that takes responsibility for the initiation, management and/or financing of a clinical trial.

For guidance on completion of this form and the required associated documentation, please see the UTAS Clinical Trials Governance [webpage](http://www.utas.edu.au/research-admin/research-integrity-and-ethics-unit-rieu/clinical-trial-governance/clinical-trial-governance-elements) or contact the College of Health and Medicine Research Hub at Clinical.Trials@utas.edu.au.

A draft of this form can be submitted at the time of, or prior to, ethics submission. There is no deadline for the submission of governance applications.

Your trial may only commence once this form and all associated documents are finalised, and authorisation has been granted by the Deputy Vice-Chancellor (Research).

Submit this form and all attachments to Clinical.Trials@utas.edu.au.

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| Part A | **Trial Details** |
|  | **Trial title** |  |
|  | **Principal Investigator***Must have University of Tasmania affiliation* | Name: Position: University employment type: *(employee, adjunct, clinical or associate – see:* [*Adjunct, Clinical and Associate Titles Procedure*](https://www.utas.edu.au/academic-division/academic-leadership-and-performance/adjunct-and-clinical-titles)*)*College: School/Institute: Phone: E-mail: Other affiliations: *e.g. Royal Hobart Hospital* |
|  | **Trial description** | *Please provide a brief description (maximum 300 words) of the trial using layperson’s terms. The summary should include who the participants will be, what the intervention is and what health outcome(s) will be measured. This summary will be provided to the Deputy Vice-Chancellor (Research) for consideration when reviewing your trial.* |
|  | **Site details** | [ ]  Single-site or [ ]  Multi-site:[ ]  Australian site(s)[ ]  International site(s) – additional insurance may be required |
| If you indicated this is a multi-site trial, list each of the sites the University is collaborating with, including the Principal Investigator’s (PI) name.*An agreement will be required between the University and each site, see Part B below* | Site 1: PI name and email: Site 2: PI name and email: Site 3: PI name and email: *Repeat as required* |
|  | **Anticipated number of participants** | For the entire trial:  | At each site listed above in Q3Site 1: Site 2: Site 3:*Repeat as required* |
|  | **Intervention type** | [ ]  Drug [ ]  Education[ ]  Device [ ]  Vaccine[ ]  Procedure [ ]  Other:  | If drug/device, please provide the name:  |
|  | **Importing therapeutics** | If drug or vaccine is selected in question 7, please indicate if it is:[ ]  A natural product (non-synthetic)[ ]  Imported from overseasIf both boxes are ticked, please refer to the Importing Biological Materials section of the UTAS Biosecurity [webpage](https://www.utas.edu.au/research-admin/research-integrity-and-ethics-unit-rieu/biosecurity) and contact biorisk.management@utas.edu.au for advice. |
|  | **Regulatory** | Does the trial require acknowledgement by the TGA via a [CTN or CTA](https://www.tga.gov.au/clinical-trials)? | [ ]  Yes[ ]  NoIf yes, please complete the [CTN form](https://www.utas.edu.au/research-admin/research-integrity-and-ethics-unit-rieu/clinical-trial-governance/clinical-trial-governance-elements) |
|  | **Trial phase** | [ ]  Pilot [ ]  Phase I [ ]  Phase II [ ]  Phase III[ ]  Phase IV/post marketing surveillance [ ]  N/A |
|  | **Invasive nature of trial** | [ ]  Yes, please provide details: *e.g. blood tests, x-ray, MRI*[ ]  N/A |
|  | **Anticipated number of participants** | For the entire trial: |
|  | **Overall trial timelines** | Expected commencement date: Expected close-out date:  |
|  | **Human Research Ethics Committee approval** | UTAS HREC reference number: UTAS HREC approval date: [ ]  *UTAS HREC approval letter provided with this form*  |
| [ ] For non-UTAS sites, please confirm you have provided HREC approval letters for each site listed in Part A Question 4. |
|  | **Clinical trial registration** | Register: Registration number: *All Clinical Trials must be registered on an* [*ICMJE accepted registry*](http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/)*, e.g.* [*ANZCTR*](http://www.anzctr.org.au/Default.aspx)*.* |

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| Part B | Legal, Finance and Risk |
|  | **Clinical Trial Research Agreement** | Please indicate the type of agreement to be used between the University of Tasmania (as sponsor) and the clinical trial site(s):[ ]  [Medicines Australia Collaborative/Co-operative Research Group Agreement](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/) (can be used for Institutionally sponsored trials and collaborative or co-operative trials)[ ]  [Medical Technology Association of Australia Standard Agreement](https://www.mtaa.org.au/clinical-investigations-research-agreements) (used for device trials)[ ]  [Medicines Australia Phase 4 Clinical Trial Agreement](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/) (used for phase 4 trials)[ ]  NHMRC Multi-Institutional Agreement for Clinical Trials (used for University of Tasmania sponsored trials, or collaborative or co-operative research where there is NHMRC funding)[ ]  Other: *Any agreements not listed here, or special conditions to these agreements, will require legal review. Please liaise with your Funding Officer to facilitate this review.* |
|  | **Budget and finance** | Does the University of Tasmania have the appropriate budget to undertake the study at the trial site(s)?[ ]  Yes, please state the name of the funding body and the amount: [ ]  No, please describe how any budget shortfall will be covered:  |
|  | **Risk assessment** | Are there any significant institutional risks from your risk assessment that might impact the trial or the University of Tasmania?*This includes risks to participants as well as to researchers and the University (e.g. key person dependencies, financial risk, Intellectual Property, contractual risk, etc.). This does not include ethical risks; these are dealt with via the ethics application.*[ ]  Yes, please detail the risks and how you propose to mitigate them: [ ]  No |
|  | **Insurance**  | All clinical trials must have appropriate insurance cover. If your trial involves any of the below, please tick the appropriate box as you may need prior approval or additional insurance (to be paid for from trial funds) from the UTAS insurer. The CHM Research Hub will assist you to determine the insurance requirements for your trial if they involve any of the below.[ ]  COVID-19[ ]  Neonates[ ]  Pregnant women[ ]  International sites – note: if you have international sites, you must include the [COVID-19 insurance exclusion information](https://www.utas.edu.au/research-admin/research-integrity-and-ethics-unit-rieu/clinical-trial-governance/clinical-trial-governance-elements) in the participant consent process.  |
|  | **COVID-19** | For all trial sites, the Lead Principal Investigator (PI) is required to confirm the following:[ ]  a COVID safe plan is in place for each site;[ ]  the Lead PI has sighted each plan; and[ ]  each plan is appropriate and all COVID risks will be managed. |

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| Part C | Personnel Details |
|  | **Employment** | [ ]  Please confirm that all personnel involved in the conduct of the trial have notified their respective employer(s) of their participation. |
|  | **Good Clinical Practice (GCP)** | It is required that all Principal/Chief Investigators maintain current Good Clinical Practice (GCP) training throughout the lifecycle of their trial.Please provide evidence of GCP training for the trial Principal/Chief Investigators for all sites.It is recommended that key staff, such as Clinical Trial Coordinators and Project Officers, also maintain current GCP training. | Date of training: *Please provide a copy of the certificate.* |

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| Part D | Declarations |
|  | Principal InvestigatorI confirm that the above information is accurate and that the trial will continue in accordance with the Human Research Ethics Committee approved protocol and any approved amendments, and in compliance with the *Australian Code for the Responsible Conduct of Research*, the *NHMRC National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) and the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)* Annotated with TGA comments (DSEB July 2000).Sponsor and investigator responsibilities relating to safety monitoring and reporting are delegated to the Principal Investigator for all clinical trials sponsored by the University of Tasmania (also referred to as Investigator Initiated Trials) and conducted under the Clinical Trial Exemption (CTX) or Clinical Trial Notification (CTN) schemes. This is in accordance with the National Health and Medical Research Council Guidance [Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods (November 2016)](https://www.nhmrc.gov.au/sites/default/files/images/NHMRC-guidance-safety-monitoring-and-reporting.pdf): items 1 (Responsibility of the Sponsor, p7 and p17) and 2 (Responsibilities of the Principal Investigator, p10 and p19) in Section C for both Products and Devices.The CHM Research Hub (clinical.trials@utas.edu.au) will manage any reporting to the Therapeutic Goods Administration; however, it is the responsibility of the Principal Investigator to provide the Research Hub with the relevant information to undertake this reporting.I agree to personally supervise the clinical trial at the site listed in Part A, Question 4 and I acknowledge my obligations with respect to monitoring participant safety and record management.I agree to ensure all Associate Investigators and others assisting in the conduct of the trial are informed of their obligations in meeting the above requirements. | Name: Signature: Date:  |
|  | Approving Authority*This declaration must be completed by the Head of School/Institute involved in hosting the trial at the University of Tasmania, listed at Part A Question 4 of this form. Where an Investigator for the study is also the Head of School/Institute, approval must be sought from the person to whom the Head of School/Institute is responsible.*I am authorised to represent the School/Institute listed in Part A Question 4 of this form and give authorisation for this trial to proceed.I have read this application form and have discussed the resource implications of the clinical trial with the Principal Investigator.I certify that the Principal Investigator and other investigators involved in the project have the necessary skills, training and experience to undertake their roles and, where necessary, appropriate training and supervision has been arranged.I certify that there are suitable and adequate facilities and resources for the clinical trial to be conducted at this site as proposed, and that they are available for the duration of the trial. | Name: Signature: Date:  |

**Next steps**

Once this Governance Application Form is complete with all necessary attachments, the CHM Research Hub will prepare a briefing for the Deputy Vice-Chancellor (Research) (DVCR) with a recommendation to authorise trial commencement at the University of Tasmania. If there are other sites involved in the conduct of the trial, they must undertake a site-specific assessment/governance review process at their own site.

Once DVCR authorisation has been received, the CHM Research Hub will release the Clinical Trial Site Authorisation certificate and the trial may commence.

**Checklist**

Submit these items (can be in draft) as early as possible (before or at the same time as HREC submission).

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| **Documents Required** | **Yes** | **N/A** |
| Standard Form of Indemnity (Medicines Australia or MTAA Standard Form of Indemnity) for the University of Tasmania | [ ]  | [ ]  |
| Insurance Certificate | [ ]  | [ ]  |
| Clinical Trial Notification (CTN) | [ ]  | [ ]  |
| Standard Clinical Trial Research Agreement or other collaborative agreement | [ ]  | [ ]  |
| Evidence of Good Clinical Practice training from all relevant persons | [ ]  | [ ]  |
| HREC certificates for all sites | [ ]  | [ ]  |