CLINICAL TRIALS PROCEDURES 2016

Issued by:	Director, Research Integrity and Ethics Administration
Dated:	2 December 2016
Last amended:	13 June 2017 (administrative amendments only)
	1 June 2023 (administrative amendments only)
	22 April 2024 (administrative amendments)
Signature:	
Name:	Dr Margaret Faedo
Current policy approver:	Deputy Vice-Chancellor (Research)

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1 Purpose and application

(1) These procedures are to give effect to the Clinical Trials Policy ("the policy").

(2) These procedures apply to all clinical trials to which the policy applies.

2 Commencement

These procedures commence on 1 January 2017.

3 Interpretation

(1) Words and phrases used in these procedures and not otherwise defined in this document have the meanings they have in the policy.

(2) In these procedures:

Contracts Manager – Clinical Trials	means the occupant of that position within the office of Commercial Development and Industry Partnerships (CDIP) of the Research Portfolio.
risk assessment	means an assessment of the risks to the University posed by a clinical trial conducted consistently with the provisions of clause 6.
risk assessment application	means the risk assessment application form specified by the Clinical Trials Office, which may be an online format. **Note:** See the Research Portfolio website: Risk Assessment application.
site specific assessment	means an assessment of the clinical trial governance arrangements at a site at which a clinical trial will be conducted, conducted consistently with the provisions of clause 7.

site specific assessment application means the site specific assessment application form specified by the Clinical Trials Office, which may be an online format.

Note: See the Research Portfolio website: Site Specific Assessment application.

4 Overview

Schedule 1 contains a diagrammatic summary of the approval process set out in these procedures.

5 Applying for approval

(1) A researcher seeking approval for a clinical trial must complete each of the steps specified in this clause which are appropriate to the proposed clinical trial.

(2) The required steps, which may be commenced in any order and may be undertaken in parallel. are:

(a) ethics approval;

(b) risk assessment;

(c) site specific assessment (in appropriate cases); and

(d) contracts (in appropriate cases).

(3) **Ethics approval** is required for all clinical trials. This requires that:

(a) the clinical trial is approved by the University's Human Research Ethics Committee (or other accredited ethics committee which, for Australia, must be registered with the National Health and Medical Research Council); or

(b) the CI or PI has provided the Clinical Trials Office with written agreement not to commence the clinical trial until the approval referred to in subclause 5(3)(a) has been granted.

Note: See the Human Ethics website for more information.

(4) **Risk assessment** is required for all clinical trials. This requires the CI or PI (or their designated representative) to submit a completed risk assessment application, including all supporting documents required by that application, to the Clinical Trials Office.

(5) **Site specific assessment** is required if the University is to be a site of the clinical trial. This requires the CI or PI (or their designated representative) to submit a completed site specific assessment application, and all supporting documents required by that application, to the Clinical Trials Office.

Note: See clause 6 of the policy for definition of site.

(6) **A contract** is required if a third party is to:

(a) participate in the conduct of;

(b) provide financial support for; or

(c) provide products for use in,

the clinical trial.

(7) In such cases the CI or PI (or their designated representative) must submit a request to the Contracts Manager – Clinical Trials for preparation of an appropriate clinical trial contract, or contracts, between the University and any third parties.

Note: Examples include contracts with third party sponsors (where the University is a site), third party sites (where the University is the sponsor), overseas lead or local sponsors, third party funding (other than government or not for profit) or investigational product providers, research collaborators, pharmacy, storage, transport or analysis service providers and suppliers of equipment and consumables.

6 Risk assessment

(1) On receipt of a risk assessment application and supporting documents, the Clinical Trials Office must assess the risks to the University posed by the clinical trial and categorise it as one of the following:

(a) low;

(b) medium;

(c) high; or

(d) very high.

(2) The Clinical Trials Office may require the applicant to submit further information to assist with its risk assessment.

(3) Where a clinical trial is rated as high risk or greater:

(a) the Clinical Trials Office must refer it to the Clinical Trials Advisory Committee, which will:

(i) provide advice to the CI or PI in relation to the risks; and

(ii) where possible, assist them to develop a plan to mitigate those risks;

(b) after consultation with the Clinical Trials Advisory Committee, the CI or PI may resubmit a revised risk assessment application and supporting documents to the Clinical Trials Office for reassessment; and

(c) no later than 12 weeks after the Clinical Trials Office refers a clinical trial to the Clinical Trials Advisory Committee, the Clinical Trials Office must refer the clinical trial to the Director of Research Integrity and Ethics Administration who must:

(i) consider any further materials submitted, including any risk mitigation plan;

(ii) determine a final risk rating; and

(iii) determine the recommendation to the relevant delegate about whether or not the University should participate in the proposed clinical trial.

(4) The Clinical Trials Office must then provide:

(a) the risk rating;

(b) an explanation of the basis for the rating; and

(c) the recommendation to the relevant delegate about whether or not the University should participate in the proposed clinical trial;

to each of:

(d) the relevant delegate, for consideration in determining whether or not to approve the clinical trial; and

(e) the Contracts Manager – Clinical Trials, for consideration in preparing any required contracts if the clinical trial is approved.

7 Site specific assessment

(1) On receipt of a site specific assessment application and supporting documents, the Clinical Trials Office must:

(a) conduct a site specific assessment of the proposed University site; and

(b) determine a recommendation about whether the University should act as a site for the proposed clinical trial.

(2) The Clinical Trials Office must then provide the relevant delegate with:

(a) its recommendation; and

(b) an explanation of the basis of the recommendation.

8 Contracts

(1) The Contracts Manager – Clinical Trials will assist CIs and PIs (or their designated representatives) to identify the contracts required for a proposed clinical trial.

(2) The Research Grants and Contracts team in the Research Portfolio manages all grant funding agreements, for example with the NHMRC or Cancer Australia.

Note: See the Research Portfolio website for more information.

(3) Funding agreements between the University and a government or not-for-profit organisation to support a clinical trial are not considered clinical trial contracts for the purposes of these procedures and may be processed in the same manner as other grant agreements.

(4) The exception in clause 8(3) only applies to the funding agreement itself. The Contracts Manager – Clinical Trials will process any related contracts that are required to be entered into with third parties involved in the clinical trial, for example Multi-Institution Agreements and Research Collaboration Agreements.

(5) On receipt of a request for a clinical trial contract, the Contracts Manager – Clinical Trials:

(a) may request further supporting documentation or information as they consider appropriate from the CI or PI (or their designated representative), the Clinical Trials Office, or others;

Note: Researchers are encouraged to provide any proposed draft contracts and copies of any pre-existing relevant contracts (e.g. funding agreements and collaborations agreements) as early as possible to streamline the contract process.

(b) will review or prepare any necessary clinical trial contract or contracts; and

(c) will co-ordinate the clinical trial contract process, including negotiating with the relevant third parties where required, in consultation with the CI or PI and Office of General Counsel.

(6) Where practicable and relevant, the Contracts Manager – Clinical Trials may use template clinical trial contracts approved by Office of General Counsel.

(7) The Contracts Manager – Clinical Trials must consult with the Office of General Counsel if:

(a) a suitable template contract is not available;

(b) amendments to a template contract are required;

(c) legal review of a third party's contract is required; or

(d) other legal advice is required.

(8) The Contracts Manager – Clinical Trials will make a recommendation to the relevant delegate about whether or not the University should enter into a proposed contract, taking into consideration:

(a) the preparation, review and negotiation of the proposed clinical trial contract; and

(b) the risk rating; and

(c) any further supporting information provided by the Clinical Trials Office.

9 Approval by the relevant delegate

(1) The relevant delegate may approve the University's participation in a clinical trial by:

(a) signing a clinical trial contract for the relevant clinical trial activity, after the process set out in these procedures is followed;

(b) signing a letter confirming the clinical trial is authorised to be conducted on a University site, after the process set out in these procedures is followed; or

(c) signing a document confirming the clinical trial is approved under clause 8(1) of the policy.

Note: To identify the relevant delegate, see *University of Sydney (Delegations of Authority) Rule*

(2) The relevant delegate may provide approval subject to conditions.

(3) Any substantive changes to an approved clinical trial must be submitted for re-approval with these procedures.

10 Regulatory notification

If an approved clinical trial:

(a) involves the University as a sponsor; and

(b) is required by law to be notified to the TGA;

each of the steps specified below must be completed before any human participants are enrolled:

(c) the CI or PI must complete and submit to the Clinical Trials Office a CTN data capture form;

Note: See the Research Portfolio website.

(d) the Clinical Trials Office must submit a formal Clinical Trial Notification to the TGA, and

(e) the CI or PI (or their representative) must arrange to pay the applicable invoice from the TGA by the due date.

NOTES

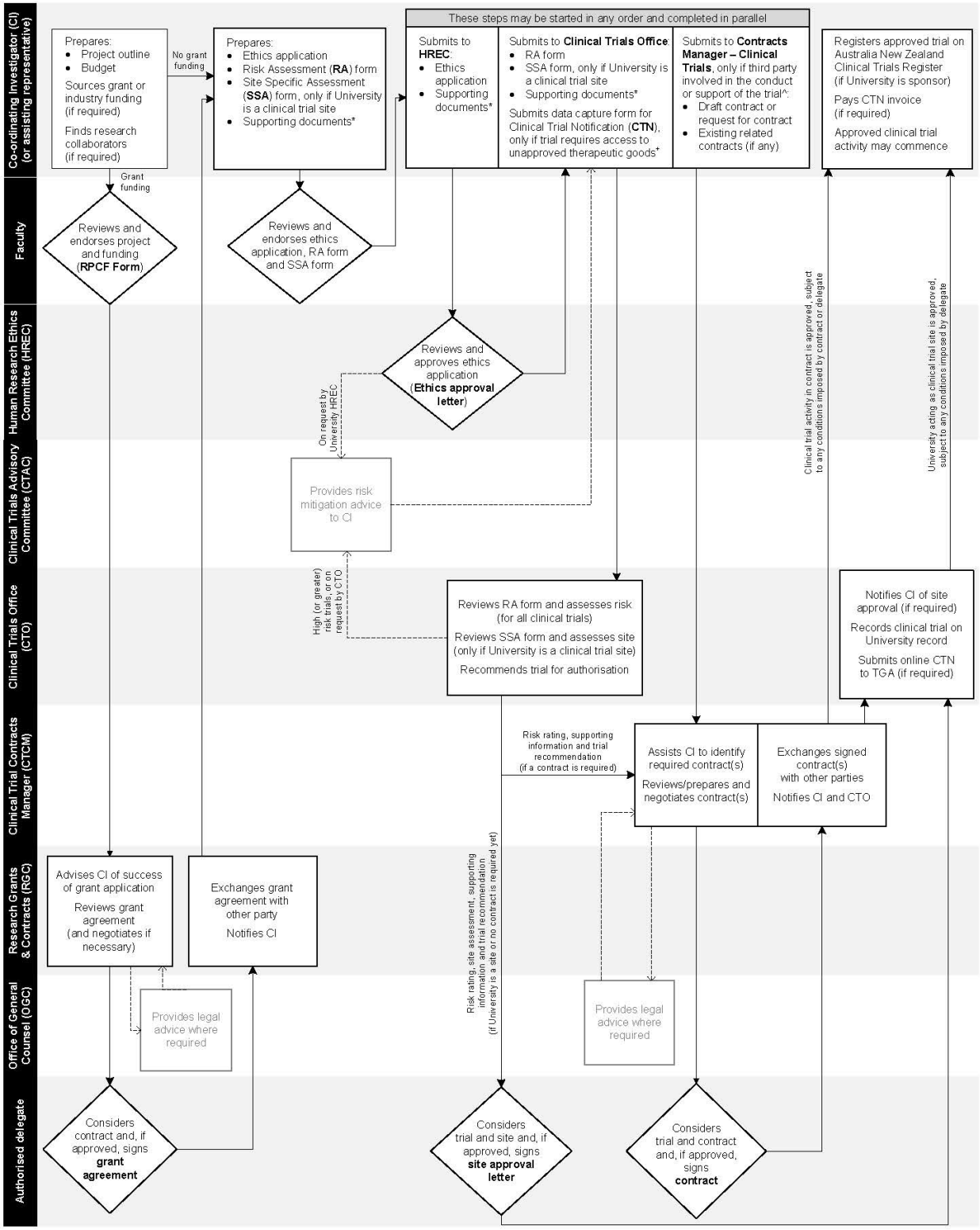
Clinical Trials Procedures 2016

Date adopted:	2 December 2016
Date registered:	12 December 2016
Date commenced:	1 January 2017
Date amended:	13 June 2017 (administrative amendments) 1 June 2023 (administrative amendments) 22 April 2024 (administrative amendments)
Original administrator:	Director, Research Integrity and Ethics Administration
Current policy owner:	Pro Vice-Chancellor (Research)
Review date:	3 years from the date of commencement of these procedures.
Rescinded documents:	
Related documents:	*University of Sydney (Delegations of Authority) Rule* *Clinical Trials Policy*

AMENDMENT HISTORY

Provision	Amendment	Commencing
Related documents	Updated reference to *University of Sydney (Delegations of Authority – Administrative Functions) Rule 2016*	13 June 2017
Related documents	Replaced ‘University of Sydney (Delegations of Authority – Administrative Functions) Rule 2016’ with ‘University of Sydney (Delegations of Authority) Rule 2020	1 June 2023
Throughout	Administrative amendments to remove the year in policy references.	22 April 2024

SCHEDULE 1 - CLINICAL TRIAL APPROVAL PROCESS MAP



* See the relevant application form. These may include: Protocol (GCP-compliant research plan), itemised budget, Patient Consent Forms (PCF), Patient Information Sheets (PIS), Investigator's Brochure (IB) or Approved Product Information (API) for each such medicine and/or medical device used in the clinical trial, list of responsibilities of the University and third parties involved in the clinical trial, short form curriculum vitaes of researchers and evidence that researchers have appropriate GCP training.

^ This is only required if the clinical trial is reportable to the Therapeutic Goods Administration (TGA), e.g. a clinical trial of a new medicine or medical device. Research groups may submit this form to the Clinical Trials Office closer to project start as details can change in the intervening period.

\+ The Contracts Manager – Clinical Trials can help identify the contract or contracts that are required, for example contracts with third party sponsors (where the University is a site), third party sites (where the University is the sponsor), overseas lead or local sponsors, third party funding (other than government or not for profit) or investigational product providers, research collaborators, pharmacy, storage, transport or analysis service providers and suppliers of equipment and consumables. Note that grant agreements are processed by Research Grants and Contracts and not the Contracts Manager – Clinical Trials.