

ADCTN Clinical Trial Protocol Review Investigator Guide

Enhancing Your Clinical Trial Protocol

The Australian Diabetes Clinical Trials Network (ADCTN) offers investigators a structured review process to improve clinical trial protocols before submission to funding bodies or ethics committees. This process provides:

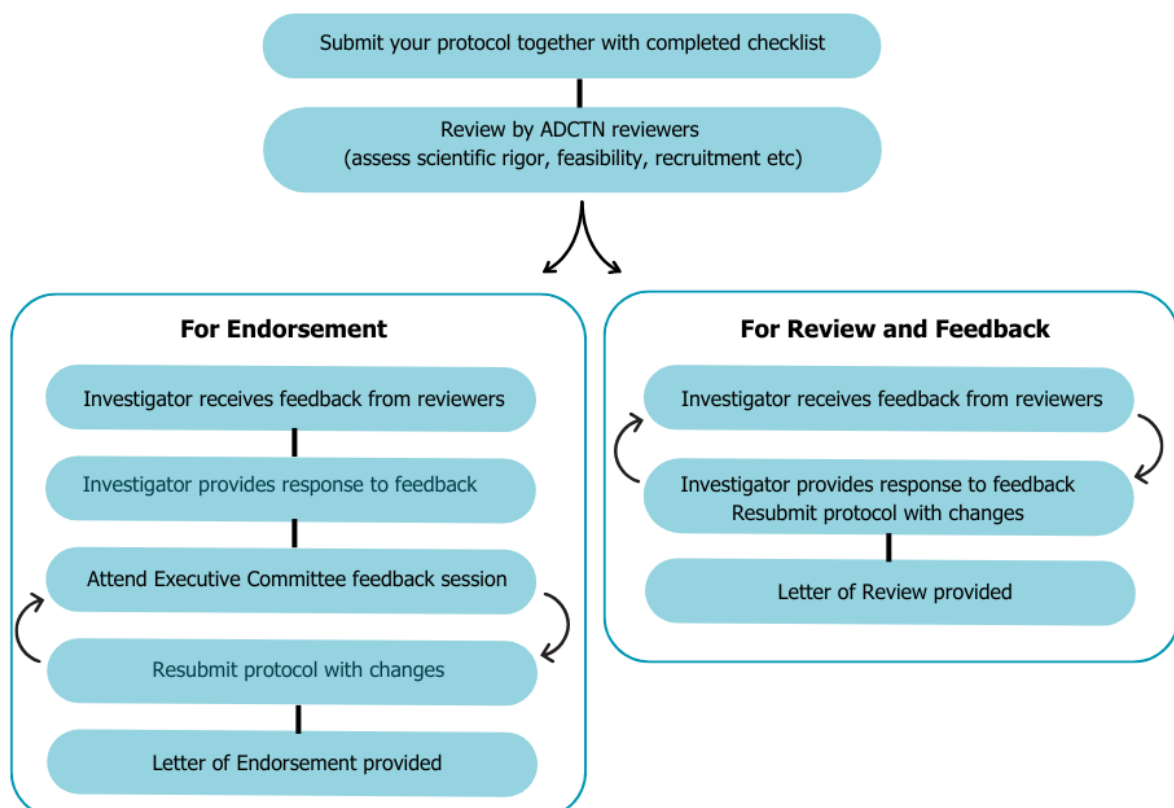
- Expert scientific, feasibility and clinical feedback from experienced diabetes researchers.
- Lived experience perspectives to enhance trial relevance and inclusivity.
- An opportunity to discuss protocol design with the ADCTN Executive Committee.

Protocols can be submitted for either:

- Expert review with feedback (e.g. in preparation for grant submissions)
- Formal endorsement

How the Process Works

Please note: Protocols need to be in final submission draft format, early drafts will not be reviewed. Due to demand, not all protocols may be able to be assessed. We will notify investigators if a submission cannot be reviewed in the current review cycle.



For Formal Endorsement

1. **Submit Your Protocol**
 - Email your **draft protocol** (submission format) and the completed **ADCTN Investigator Checklist** to ADCTN-info@unimelb.edu.au by the submission deadline.
 - If applicable, check with your study funder to ensure they are happy for the protocol to be reviewed.
2. **Review by the ADCTN Executive Committee**
 - Your protocol will be reviewed confidentially by ADCTN Executive Committee.
 - Reviewers will assess scientific rigor, feasibility, recruitment strategies, and diversity considerations.
3. **Receive Feedback**
 - A summary of reviewer feedback will be provided before your scheduled Executive Committee meeting.
 - You will be required to provide a response addressing the reviewer feedback prior to the meeting.
4. **Attend a Feedback Discussion**
 - Investigators present a high-level summary of the study at the ADCTN Executive Committee meeting.
 - Opportunity to discuss feedback, ask questions, and refine trial design.
 - A summary of feedback will be provided after the meeting, including next steps.
5. **Revise and refine protocol based on feedback**
 - Resubmit your protocol with a list of changes made.
 - *Note* you may be required to re-present at a following meeting/s.
6. **Decision on endorsement made by Executive Committee**
 - If the Executive Committee is satisfied with the protocol, a formal Letter of Endorsement will be issued
7. **Post-Review & Follow-Up**
 - Investigators are invited to complete a short survey to help improve the process.
 - An annual follow-up survey will track study outcomes and impact (e.g., funding success, trial completion).

For Expert Review and Feedback

1. **Submit Your Protocol**
 - Email your **draft protocol** (submission format) and the completed **ADCTN Investigator Checklist** to ADCTN-info@unimelb.edu.au by the submission deadline.
 - If applicable, check with your study funder to ensure they are happy for the protocol to be reviewed.
2. **Review by the ADCTN Reviewer Panel**
 - Your protocol will be reviewed confidentially by ADCTN Reviewer Panel members.
 - Reviewers will assess scientific rigor, feasibility, recruitment strategies, and diversity considerations.
3. **Receive Feedback**
 - A summary of reviewer feedback will be provided to you.
4. **Revise and refine your protocol**
 - You will be required to provide a response addressing the reviewer feedback.
 - Resubmit your protocol with a list of changes made.
5. **Decision on review made**
 - If the Reviewer Panel is satisfied with the protocol, a formal Letter of Review will be issued
6. **Post-Review & Follow-Up**
 - Investigators are invited to complete a short survey to help improve the process.
 - An annual follow-up survey will track study outcomes and impact (e.g., funding success, trial completion).

Expert Review and Feedback: 2025 Submission deadlines

Submission deadline	Friday 9 May 2025	Friday 4 July 2025	Friday 5 September 2025	Friday 31 October 2025
Investigator: - Receive written feedback from reviewers - Provide a response to feedback	Friday 30 May – Monday 9 June 2025	Friday 25 July – Monday 4 August 2025	Friday 26 September – Monday 6 October 2025	Friday 21 November – Monday 1 December 2025

Formal Endorsement: 2025 Submission deadlines and timelines*

Submission deadline	Friday 9 May 2025	Friday 4 July 2025	Friday 5 September 2025	Friday 31 October 2025
Investigator: - Receive written feedback from reviewers - Provide a response to feedback prior to Executive Committee meeting	Friday 30 May – Monday 9 June 2025	Friday 25 July – Monday 4 August 2025	Friday 26 September – Monday 6 October 2025	Friday 21 November – Monday 1 December 2025
Present at Executive Committee meeting	Tuesday 10 June 2025	Tuesday 5 August 2025	Tuesday 7 October 2025	Tuesday 2 December 2025

*Dates are subject to change

Why Participate?

- Strengthen your protocol with expert and lived experience feedback.
- Improve feasibility and recruitment strategies to enhance trial success.
- Improve competitiveness of your funding applications.
- Access a national network of diabetes research and clinical trial experts.

For further information, details of the next review cycle, or to submit your protocol, contact ADCTN-info@unimelb.edu.au.