



Government of Western Australia
Child and Adolescent Health Service



CAHS Research Companion is led by:

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CAHS Research Companion is a service
of the CAHS Research Department

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Perth Children's Hospital

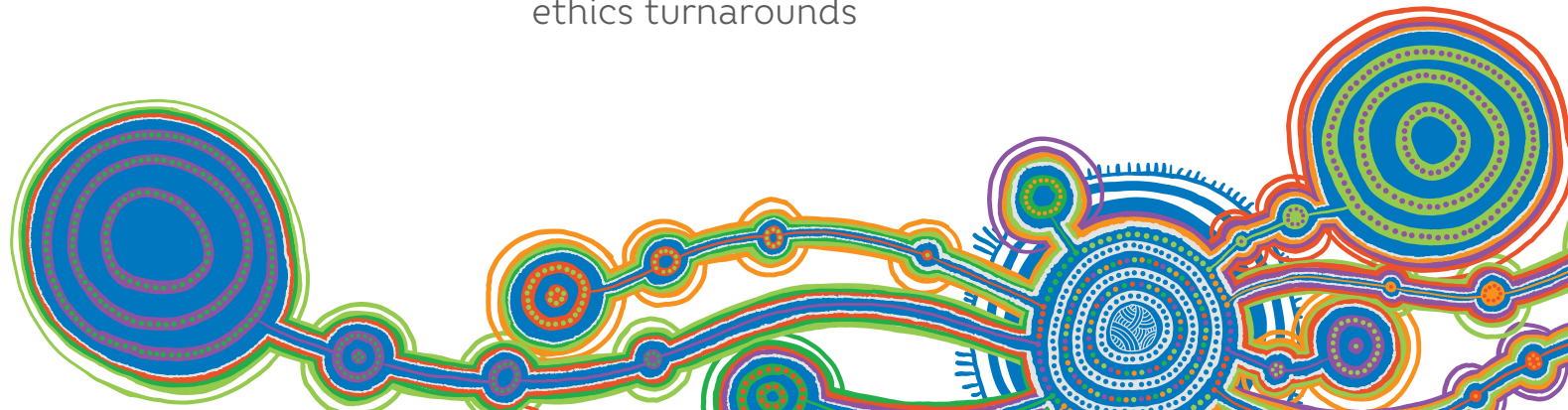
15 Hospital Avenue, Nedlands WA 6009

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CAHS Research Companion

Expediting clinical trials through CAHS' regulatory
processes with smooth startups and competitive
ethics turnarounds



Welcome to Research Companion

A boutique service offered by the Child and Adolescent Health Service (CAHS) to prospective commercial sponsors and researchers.

We expedite the progress of clinical trials through CAHS' regulatory processes, with smooth start-ups and competitive ethics turnarounds.

Key to our service is the direct involvement of Research Companion's team members who maintain close contact with sponsors throughout the approval process.

Research Companion can assist with Human Research Ethics Committee (HREC) and governance preparation and liaison, as well as post-approval management support.

Except for Phase 1 studies, sponsors are notified of ethics review outcomes within 3 business days of their HREC meeting. Governance (site authorisation) outcomes are notified within 7 business days of receipt of all documentation.

CAHS is Western Australia's leading site for sponsored paediatric clinical trials.

HREC and governance package \$10,000

- ✓ Preparation and customisation of all ethics and governance documentation:
 - PICF master and site-specific versions
 - HREA and distribution of site SSAs
 - WA-specific module
- ✓ Single point of contact for ethics and HREC liaison
- ✓ Coordination of essential documentation
- ✓ Distribution of approved documents to Clinical Research Organisation (CRO)/Sponsor/Sites as required
- ✓ Governance prepared in parallel with Ethics for CAHS sites
- ✓ Submission acknowledgement from HREC Ethics Officer
- ✓ Committee review acknowledgement decision within 3 business days of meeting - includes both Clinical Trials Sub-Committee (CTS) and HREC reviews
- ✓ HREC approval within 30 days of meeting deadline (excludes Phase 1 trials)
- ✓ Submission of site-specific governance documents
- ✓ Response to any governance queries
- ✓ Governance approval within 7 days of validated submission
- ✓ *\$7,000 Ethics and Governance fee

Governance-only package \$5,500

- ✓ Preparation and customisation of all governance documentation:
 - PICF master and site-specific versions
 - HREA and distribution of site SSAs
 - WA-specific module
- ✓ Single point of contact for governance liaison
- ✓ Coordination of essential documentation
- ✓ Distribution of approved documents to CRO/Sponsor/Sites as required
- ✓ *\$3,500 Governance fee

Annual reporting package \$2,000

- ✓ Amendments
- ✓ Progress Reports
- ✓ Safety Reports



Post-approval fees

HREC review on behalf of each additional site	*\$600
Review of an amendment	*\$600
Further review of an amendment	*\$288

Amendments will receive acknowledgment of receipt on the day (within standard operating hours) and be submitted once review is finalised in consultation with the study sponsor.

Payment

Fees are payable in full on project submission or amendment. [Payment can be made using the CAHS BPOINT](#) (BPOINT number 59899). Please include the last 4 digits of your application's RGS number and a short payment description. The ethics/governance review process will not start until fees have been paid.

*All costs are in Australian dollars and exclude GST. These fees are mandatory even if not using the Research Companion service.

HREC meeting deadline

