

CORPORATE PROCEDURE:

Audits requiring WCHN Human Research Ethics Approval

DOCUMENT MANAGEMENT	
Document Number	sp2024_011
Summary	To provide guidance as to when an audit pertaining to patients/clients requires review by either the Women's and Children's Health Network (WCHN), Human Research Ethics Committee (HREC), or WCHN HREC Chair.
Applies to:	WCHN All
Exceptions	None
Replaces	sp2018_045 Audits requiring WCHN HREC Approval
Lead Writer / Key Contact	Dr Tamara Zutlevics, Patient Ethicist
Accountable Director / Oversight Committee	ED, Corporate Services, Human Research Ethics Committee
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Key Words	Audit, Human Research Ethics Committee, Research, HREC audits
Status	Active
Approved by	Philip Robinson, ED, Corporate Services
Approval Date	26 th June 2024

Compliance with WCHN Procedures is mandatory.

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Document History

Version	Date	Writer	Amendment/s	Status
V3	26/06/24	SQU	Endorsed by Philip Robinson	Final
V2.2	19/05/24	Patient Ethicist	Feedback incorporated. Scheduled review: Information incorporated into new procedure template. <ul style="list-style-type: none">• Updated reference to the revised 2023 <i>National Statement on Ethical Conduct in Human Research</i>.• Added further clarity around the definition of a research audit as opposed to research study.• Minor edits for clarity.• Updates to links.	Draft
V2	12/2018	Patient Ethicist	Scheduled review; Added <ul style="list-style-type: none">• Information incorporated into new procedure template.• New background (including NHMRC definition).• Section on triggers for WCHN HREC review.• Additional exceptions to WCHN HREC review (ii & iv).• Updated additional review process for research audits involving Aboriginal and Torres Strait Islander people.• Added section on the process for requesting medical records	Approved
V1	20/08/13	Patient Ethicist	Feedback incorporated	Approved

MANAGER RESPONSIBILITIES:

Managers are responsible for:

- ensuring staff are aware of this procedure; and
- have the skills and knowledge to undertake the actions described; and
- escalating any issues with the implementation of this procedure through the appropriate mechanism.

WCHN Zero Tolerance to Racism

The Women's and Children's Health Network (WCHN) is committed to ensuring Aboriginal and/or Torres Strait Islander staff, volunteers, consumers and visitors to the WCHN are able to work, and access health services in an environment that exemplifies respectful relationships and is free of racism, race discrimination and race-based harassment. This applies equally to staff, volunteers, consumers and visitors of any race or cultural background.

WCHN White Ribbon Commitment

The Women's and Children's Health Network (WCHN) recognises violence against women as a human rights issue that must be addressed in the workplace, and is committed to a zero tolerance policy towards men's violence against women in the workplace. Accordingly employees must appropriately report and respond to any such acts in the workplace, and make available appropriate support to employees who may be experiencing violence in the community.



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1 Background

The terms “peer review”, “quality assurance”, “quality improvement”, and “audit” are often used interchangeably (*Ethical Considerations in Quality Assurance and Evaluation Activities*, NHMRC, March 2014). In the current procedure the term “audit” will be used to refer to all these activities.

The NHMRC recognises that there can be uncertainty as to whether an activity constitutes research or audit as the two activities exist on a continuum. Bearing in mind this uncertainty, an audit is an “activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation” (*Ethical Considerations in Quality Assurance and Evaluation Activities*, NHMRC, March 2014).

Research is an activity that is designed to generate new knowledge that is generalizable to other instances of the same kind (that which is being investigated).

Further characteristics that tend to distinguish audits from research are as follows.

- 1) Typically, retrospective utilizing already collected data.
- 2) For internal institutional purposes.
- 3) The intention of the activity is to directly assess and/or improve service provision.
- 4) The activity is conducted by a person who normally has access to the patients’ information to which access is sought such as medical records.
- 5) The activity does not increase or add to the risk and/or burden of patients.
- 6) The findings are not typically generalizable beyond the given institution.

There are three pathways for the approval or endorsement of audits at the WCHN.

- i. WCHN HREC or WCHN HREC Chair review for research audits.
- ii. Endorsement by the relevant senior clinician for non-research audits.



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- iii. Endorsement by organisational and/or divisional committees that oversee *National Safety and Quality Health Services Standard* for non-research audits.

The current procedure is concerned with the first pathway only; WCHN HREC or WCHN HREC Chair review audits.

Please note that other non-audit applications to the WCHN HREC are

- i. Low and Negligible Risk research (LNR)
- ii. Greater than LNR research

Both applications are made via [GEMS](#) on the National Ethics Application Form (HREA). For more information on the process regarding HREA applications to the WCHN HREC see

<http://www.wch.sa.gov.au/research/committees/humanethics/index.html>.

2. Triggers for WCHN HREC review of Audits

As per the NHMRC guidelines, triggers for choosing the WCHN HREC or WCHN HREC Chair review pathways include:

- i. Where the activity potentially infringes the privacy or professional reputation of participants, providers, or organisations.
- ii. Secondary use of data—using data or analysis from Audit activities for another purpose.
- iii. Gathering information about the participant beyond that which is routinely collected.
- iv. Testing of non-standard (innovative) protocols, equipment, or devices.
- v. Targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of the data collected or analysed as part of the main QA/evaluation activity.

Where one or more of the triggers above apply, the guidance provided in the *National Statement on Ethical Conduct in Human Research, 2023* should be followed.

3. Examples of exceptions to WCHN HREC or WCHN HREC Chair review are listed below.

If in any doubt as to whether an audit project falls into the category of an exception to WCHN HREC or WCHN HREC Chair review please refer to the Chair of the WCHN HREC or Research Secretariat for advice.

- i. Audits required for compliance by the Federal or State Government.
- ii. Audits which are required for compliance with regulating bodies such as the *National Association of Testing Authorities, Australia* (NATA).
- iii. Audits pertaining to health service accreditation processes. For example, audits seeking to fulfil the requirements of the *National Safety and Quality Health Service Standards* (NSQHS).
- iv. Audits which evaluate compliance with written documented clinical pathways/guidelines/standards adopted by the WCHN.



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4. Distinguishing WCHN Chair review audits from WCHN HREC review audits

4.1 WCHN Chair review audit

Chair Review audits fall into two categories:

1. Audits which

a) access and use existing de-identified data/information, (or potentially identifiable data/information together with a signed assurance that the data/information will not be linked back to identifiable information)

and

b) answer 'No' to questions 1 - 9 in the [WCHN HREC Audit Application Form](#)

2. Audits where

a) consent has been given. (Note: Retrospective consent is sometimes problematic due to privacy concerns encountered by contacting patients/clients once they have left the service.)

and

b) answer 'No' to questions 1–9 in the [WCHN HREC Audit Application Form](#).

4.2 WCHN HREC review audit

WCHN HREC Review audits fall into three categories:

1. Audits which propose to access or use identifiable data/information without patient consent, and which do not fall into the noted *exception* (Section 3).

2. Audits which propose to collect new sensitive data/information, and which do not fall within the noted *exception* (Section 3).

3. Audits which answer 'Yes' to any of the 9 questions in the [WCHN HREC Audit Application](#) form and which do not fall within the noted *exception* (Section 3).

Note: *Persons wanting to repeat an audit which has received ethics approval by either the Chair of the WCHN HREC or the full Committee beyond the approval time granted, should submit an extension request which will be reviewed by the WCHN HREC Chair.*

5. Submission of WCHN Chair review audits and WCHN HREC review audits

1. Complete **one** copy of the [Audit Application](#) form.

2. Ensure all relevant documents are submitted along with the [Audit Application](#) form. Relevant documents may include surveys/questionnaires, brief information sheet, confidentiality agreements, and police checks.

3. Ensure both the divisional certification and the investigator declarations are completed on the [Audit Application](#) form (p4).

Note: *Please note that divisional certification should not be provided by the chief investigator if the chief investigator and Head of Department is one and the same person. In such cases divisional certification should be provided by a delegate or Divisional Director.*



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4. Submit documents to:
Research Information Officer
Research Secretariat
Women's and Children's Health Network
2nd floor, Samuel Way Bldg
72 King William Rd, North Adelaide, SA 5006
ph: 08 81616521 fax 08 8161 8177
Email: Luke.Fraser2@sa.gov.au

6. WCHN HREC audits involving Aboriginal and/or Torres Strait Islander People

The WCHN HREC distinguishes three categories of projects involving Aboriginal and Torres Strait Islander people.

1. Audits where the focus is on a topic or disease/health burden identified as being of specific concern to Aboriginal and Torres Strait Islander peoples (based on 4.7.6 of the *National Statement, 2023*).

(Note: examples include outcome data for Aboriginal and/or Torres Strait Islander people, soliciting the views of Aboriginal and/or Torres Strait Islander people, etc).
2. Audits where the geographic location of the research is such that a significant number of the population are likely to be Aboriginal and Torres Strait Islander people; (based on 4.7.6 of the *National Statement, 2023*).
3. Audits where it is proposed to separately identify data relating to Aboriginal and/or Torres Strait Islander people in the results.

WCHN HREC audits falling into any of the above three categories will be submitted to the Director of the Aboriginal Health Division for appropriate review in addition to HREC/HREC Chair review.



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7. Review of WCHN HREC audits

1. *Chair Review* audits are reviewed by the Chair of the WCHN HREC within 2 weeks of submission.
2. *WCHN HREC* audits are reviewed by the full WCHN HREC. Audits are placed on the agenda of the next meeting of the WCHN HREC. For an audit to be considered by the committee, the application needs to be lodged with the Research Secretariat generally two weeks prior to the WCHN HREC meeting; for specific information regarding submission dates please see the *WCHN Meeting Dates* on the WCHN internet.

Note: The WCHN HREC does not typically grant approval for non-WCHN persons to access identifiable patient/client information without consent; for potential exceptions please see Section 9.1.

8. Public interest case

Those audits which propose to access personal information without consent will need to make a public interest case. (p3 *Audit Application* form).

In determining whether the public interest in the audit substantially outweighs privacy concerns, the WCHN HREC will consider the seven points below. Consequently, those submitting an audit application should consider these points when arguing a case.

In addition to addressing the seven points below, two further issues should be addressed:

- i) Why the relevant purpose cannot be achieved using de-identified or potentially identifiable data/information, and
 - ii) Why it is impractical to seek consent.
1. The degree to which the audit is necessary to the functions of the WCHN.
 2. The degree to which the audit is relevant to public health or public safety.
 3. The degree to which the audit is likely to contribute to:
 - the identification, prevention or treatment of illness/injury/disease
 - the improved delivery of health services
 - enhanced scientific understanding or knowledge.
 4. Specific consideration will be given to any likely benefits to individuals that belong to certain categories where the information may be of a particularly personal or sensitive nature; for example:
 - children and young people
 - persons with intellectual or psychiatric disability
 - persons highly dependent on medical care
 - persons in dependent or unequal relationships
 - persons who are members of collectivities
 - Aboriginal and Torres Strait Islander peoples
 - persons whose information relates to their mental or sexual health
 5. The cost of not undertaking the audit.
 6. The extent to which the data being sought are usually available to the public from the organisation that holds that data.
 7. Whether the risk of harm to an individual whose health information is to be collected, used or disclosed is minimal.



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9. Process for requesting medical records for the purpose of audit activity

9.1 Who can access WCHN medical records for the purpose of WCHN HREC audits.

In general the WCHN HREC does not give approval for non-WCHN staff to access identifiable patient information for the purpose of an audit. The following exception applies for persons not currently employed by the WCHN or on formal attachment with clearance to have access to identifiable patient information without consent.

The researcher must work within SA Health services, and

- i. If not currently working at the WCH the researcher must have recently worked at the WCH or be coming to the WCH as part of their rotation, and
- ii. The researcher must be involved in a higher training program/scheme where a research project is required to fulfil the requirements of the program/scheme, and
- iii. The research must be overseen by a WCHN employee. Ideally the WCHN employee responsible for supervision of the research will be the PI, and
- iv. The researcher must have current clearance to work with children. For WCHN, this is generally a DHS Working With Children Check, and
- v. The researcher must access, use, or otherwise deal with all WCHN information, including WCHN patient information, in keeping with SA Health and WCHN policies.

9.2 How to access WCHN medical records

Those requiring medical records for the purpose of conducting a WCHN HREC review or WCHN HREC Chair review audit will need to

- i. complete a [Request for Medical Record Form](#)
- ii. Submit form to Medical Records along with approval letter from the WCHN HREC.

10. Confidentiality Agreement

All non WCHN auditors (and those associated with the audit) accessing the following groups, or their information, must sign a *Confidentiality Agreement*;

1. Patients/clients
2. WCHN Staff

The *Confidentiality Agreement* can be downloaded from:

<http://www.wch.sa.gov.au/research/committees/humanethics/ConfidentialityAgreement.html>.

Auditors should be aware of the fact that a breach of confidentiality is an offence under Section 93 of the *Health Care Act 2008* (SA). A breach of confidentiality can occur as the result of inappropriate discussion, access to, or disclosure of any confidential information. Any such offence can result in termination of arrangements, action for damages and/or prosecution.

Consequently, the chief investigator of a research study/audit is responsible for ensuring that:

1. All non-WCHN staff working on the audit have signed a *WCHN Confidentiality Agreement* and lodged it with WCHN HREC.
2. All non-WCHN staff joining the audit after its commencement, sign and lodge confidentiality agreements as stated at (1) directly above.

Work does not commence on the research study/audit until all relevant confidentiality agreements have been signed and lodged with the WCHN HREC.



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11. Department of Human Services Working With Children Check/DCSI

All non WCHN persons conducting an audit at the WCHN require a [Working With Children Check/DCSI](#) in the following circumstances

1. If having access to personal identifiable information pertaining to patients/clients.
2. If coming onto one of the WCHN campuses in the course of conducting the audit.

Working With Children Checks/DCSI are to be provided to the Research Governance Officer for verification.



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RISK ASSESSMENT

CATEGORY	Clinical - S&Q of Consumers	Financial	Workforce - Our People / WH&S	Legislative & Compliance	Service Delivery	Reputation & Image
Consequence					Low	
Likelihood					Low	
Risk Rating					Low	
Description					Access to identifiable information without appropriate public interest case	

Overall Risk rating:	Low
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COMPLIANCE EVALUATION

Compliance Measures
HREC continues to receive Research Audit applications at approximately the current rate with some allowance for reduction in submissions due to newly introduced exceptions to WCHN HREC and/or WCHN HREC Chair reviews; enumerated in Section 3 of the current procedure.

REFERENCING	
National Standard/s	
Definitions and Acronyms:	Human Research Ethics Committee (HREC) National Association of Testing Authorities, Australia (NATA) National Health and Medical Research Council (NHMRC) National Safety and Quality Health Service Standards (NSQHS) Women’s and Children’s Health Network (WCHN) Women’s and Children’s Hospital (WCH)
Legislation:	Health Care Act 2008 (Version 1.5.2018), South Australia
SA Health:	Research Ethics and Governance Policy
References:	Ethical Considerations in Quality Assurance and Evaluation Activities, NHMRC, 2014
Related Documents:	
Consumer Health Information	

