

This is a print version of information available on the Audit Tool. The print version may be useful to use to assist health organisations in determining level of ethical review required if the organisation chooses to use the tool. The terms of use are also available for print.

## About the Tool

The Blood Service Audit Tool provides health professionals with free easy-to-use online audits. It has been developed to assist hospitals with their clinical transfusion and patient blood management audit activities. Each audit is based on national standards and/or guidelines including the National Safety and Quality Health Service Standards and the Patient Blood Management Guidelines.

New users need to create an account to access the tool. As part of this process, users are required to agree to the Audit Tool's Terms of Use. Once registered, users will have access to all active audits and will not need to re-register for subsequent audits.

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## How To Use

### General

There are a number of audits and gap analyses available; each health service organisation needs to determine which are applicable and appropriate sample sizes for each audit. An auditor may be conducting audits for their health service organisation independently (single user) or as part of a wider group or collaboration under the direction of a group administrator (audit group); see below for specific information. You can check your registration details by clicking on the Edit button in the My Data box.

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### Single User

A single user has accessed the Audit Tool independently (rather than as part of a collaboration) on behalf of their health service organisation.

A single user will be able to:

- Select and conduct any of the relevant audits for their health service organisation.
  - Download audit results into a CSV file and print audit reports, that are only available to the user and are protected by a password only accessible to the user.
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### Auditing in a Group

Audit Group Users:

- Will be sent an invitation to join the audit group by the group administrator.
- Once a user accepts an invitation to join a group, all audits they conduct in that group will be accessible to the group administrator to view and edit.
- A user in the group will be able to view the group's combined data but not other individual users' data or view who else is in the audit group.
- A user will have the option to leave the audit group at any time. If this occurs, the audits conducted while in this group will stay with the group, and will not be accessible once the user has left the group.
- When using the reporting functions, a user has the ability to compare their results against either the rest of the group, all data available for that audit in the tool or against like hospitals.
- An administrator can remove a user from the group. This may occur if the user change roles or leaves a health service.

## **Group Administrator**

Group administrators:

- Can name and create an audit group.
- Will be identifiable to every user within the group.
- Can assign group administrator ability to another user within the group.
- Can view and edit audit results from all users who have accepted to be in the audit group.
- Are able to download CSV files and reports from all users who have conducted an audit within the group.
- Are responsible for maintaining the relevancy of the group's membership:
  - are able to delete users from the group if required, for example if a user in the group changes roles or leaves the organisation, in which case may no longer have authority to access the group's results or past audits.
  - will receive notification of incorrectly entered email addresses ("bounces")
  - should review the group's membership at regular intervals such as 6 – 12 monthly.

## **Considerations for Group Auditing**

When establishing an audit group the administrator's communication plan for the members should include:

- Purpose and aim of the group
- Audit schedules
- Reporting requirements, and
- Intention of data usage.

If you are inviting members into the group who are in job sharing roles, it is preferable to use a position email. For example if James and Sharon job share a transfusion nurse position, a joint email such as Transfusionnurse@stelsewhere.com.au allows the site to keep all their audit data together and be more efficient when generating site specific reports.

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## **Will using the Audit Tool require Human Research Ethic Committee (HREC) approval?**

Each user of the Audit Tool should refer to the appropriate policy of their organisation to determine what level of oversight is required.

The Ethical Considerations in Quality Assurance and Evaluation Activities: National Health and Medical Research Council March 2014 suggest a number of considerations to assist determine the level of oversight for quality activities and triggers that may indicate when ethical review is required for a quality activity.

The NHMRC Triggers for consideration of ethical review include:

- Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.
- **Secondary use of data – using data or analysis from QA or evaluation activities for another purpose.**
- Gathering information about the participant beyond that which is collected routinely. Information may include bio specimens or additional investigations.
- Testing of non-standard (innovative) protocols or equipment.
- **Comparison of cohorts.**
- Randomisation or the use of control groups or placebos
- 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.

NB: the two highlighted dot points are applicable to the Audit Tool. See below for more information.

As included in the terms of use for the Audit Tool, data may be used by the Blood Service in research, substantiated reporting and publications. Third party requests for research shall be assessed by the Editorial Board (Audit Tool Review Group) prior to assessment by the Research and Ethics committee of the Blood Service.

The data that is collected in the Audit Tool must be non-identifiable which means that there is no information submitted in the tool that could identify a patient or a health service.

Each Audit will have some key performance indicators which will be available for comparison. The user will be able to compare their health service results for these key performance indicators against other cohorts. The choices for comparison are:

- Their own audit group if they are auditing in a group
- Other like users/ health organisations based classifications see below\*
- All national (Australian) data within the tool
- All data within the tool (which potentially could include data from countries other than Australia).

\*The User classifies each audit with the following selections Site: Public or Private Hospital, Public or Private Laboratory Geographical classification: very remote, remote, major city, inner regional, outer regional with guidance provided for classification from

<http://www.abs.gov.au/websitedbs/D3310114.nsf/home/remoteness+structure>

NB: Individual State information is not collected and hence could not be used to compare or publish State results.

The NHMRC states if your activity triggers ethical consideration then guidance provided in the National Statement on Ethical Conduct in Human Research, 2007 (National Statement) should be followed.

It is the intent of the Audit Tool that activity undertaken using this tool should involve no more than negligible to low risk for the organisation (see chapter 2 of the National Statement). This risk assessment is primarily based on the types of audits and the collection of only non-identifiable patient and organisational data.

Institutions are responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research (see Section 2: Themes in Research Ethics: Risk and Benefit, Consent, responsibilities, and Chapter 5.2: Responsibilities of HRECs, other ethical review bodies, and researchers). Research with more than a low level of risk (as defined in paragraph 2.1.6) must be reviewed by a HREC. Research involving no more than low risk may be reviewed under other processes described in paragraphs 5.1.18 to 5.1.21.

The level of review that may be appropriate for use of the Audit Tool as described in 5.1.20 of the National Statement include:

- a. Review or assessment at departmental level by the head of department;
  - b. Review or assessment by a departmental committee of peers (with or without external or independent members);
  - c. Delegated review with reporting to an HREC; or
  - d. Review by a subcommittee of an HREC
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## Summary of Data Storage

- The Audit Tool is a web site based application that can be accessible via mobile devices.
  - To access the tool a user needs to register and create a 12 character password including lower and upper case, numeric and special characters. The password is rotated 6 monthly.
  - Data entered into the tool is stored in an Australian server hosted by Amazon Web Services (AWS).
  - The data is de-identified from the users email address in the cloud.
  - The server is monitored by an external provider of the Blood Service.
  - The patching approach for the application includes; monthly monitoring of audits and as required based on activity. Patches perceived as vital/ security to the application are undertaken ASAP. Servers are monitored with Sentry (for both user and server errors), Wormly (downtime).
  - The Blood Service Administrators for the tool require two factor authentication processes when logging into the tool.
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## References

National Health and Medical Research Council, Ethical Considerations in Quality Assurance and Evaluation Activities. Australia 2014

National Health and Medical Research Council, National Statement on Ethical Conduct in Human Research. Australia 2007 (updated 2015).