Accessing testsafe data for audit, evaluation and research
Guidelines for Reviewers

Introduction

Information held in the testsafe repository has the potential to be used for research, audit or evaluation activity aimed at improving the provision of health care services to the population served by the four DHBs represented by testsafe.

To ensure compliance with the testsafe privacy framework and legislative requirements it is important to ensure that any requests to access testsafe data for the purposes of research, audit or evaluation are appropriate. This includes assessing if the data can be obtained from source, the scientific merit of the application, the credentials of the data requestors, the purpose of the request, how the information will be encrypted and used, and to ensure that the appropriate local and national approvals have been obtained.

The purpose of this document is to outline some key criteria against which applications to access testsafe data can be assessed. Given the diversity of potential requests received by testsafe, this list is not intended to be exhaustive, however it does provide some key factors against which applications will be considered.

These review criteria should be considered alongside the *Accessing testsafe data for audit, evaluation and research: Guidelines to applicants (April 2014)* document which summarises the key information applicants should submit when requesting access to testsafe data.

Review of applications
Review Criteria

Each application will be reviewed against the criteria outlined below (amongst others if required) to assess the quality of the proposal for which the data is being requested. The assessing team reserves the right to reject any proposal they feel does not meet their criteria.

Criterion	Questions that will be considered
Applicant credentials	· Is the lead investigator or team appropriately qualified to deliver the proposed work? · Is the lead investigator or team affiliated with an appropriate organisation or institution? · Are there any conflicts of interest either identified or implied?
Background and significance	· Is the proposal relevant? · Will it add to the evidence base? · Is the relevance of the proposal supported by the evidence provided?
Aims and hypotheses	· What question is the proposal intending to address? · Are the aims and or hypotheses clearly stated and focused toward a clear issue? · Are the aims and or hypotheses appropriate or relevant? · Are the aims and or hypotheses consistent with the provided

	background • and significance of the proposal • Are the primary objectives appropriate
Methodology	General • Is the proposed methodology an appropriate approach to answering the question being asked? • Is the proposal feasible? • Are important confounders identified and controlled for? • Are other potential sources of bias identified and is there a clear explanation as to how this will be managed/addressed in the analysis? Study population • Is the study population clearly defined? • Is the study population representative of the defined population and relevant to the questions being asked? • Has a sampling framework been described? Is it appropriate? • Is the sample size calculation appropriate? Does the sample size look appropriate and feasible? • If controls are to be used, are they appropriately matched on key • variables? Are there a sufficient number of controls? Data collection • Are the identified variables appropriate to answering the proposal aims or hypotheses? • Are data quality issues addressed in the proposal? Are methods for handing the data quality issues appropriate? • If exposure to a dependant variable (s) is (are) being collected are these clearly defined and reliably measured? • If outcome measures are being collected are they appropriate, reliable and timely?
Ethical considerations	• Have any potential ethical issues been identified and adequately addressed? • Has ethical approval for the study being obtained either from the Health and Disability Ethics Committee or by the lead applicant's employing institution?
Confidentiality	• Has the encryption of the data been presented and will it pass international scrutiny? • Are approaches to ensuring the confidentiality of the data collected appropriate? • How will the data be managed when the proposal is completed, is it appropriate?

Reviews and approvals	• Have the appropriate approvals required been obtained? • Has the proposal been peer reviewed and has a copy of the peer review feedback been submitted with the applications?
Use and dissemination	• Does the application describe how findings from the proposal will be used? • Is there a plan for dissemination and is this appropriate? • For audit proposals, is there a clear description of how findings from the audit will be actioned? Is it part of a continuous cycle of quality improvement?
Funding	• See the website information for standard estimation of the time and effort required to obtain the extract • http://www.careconnect.co.nz/testsafe/healthcare-providers/provider-specific-information/

Decisions available

The Regional Éclair Management Group can decided to approve the request, provisionally approve the request pending a response to queries raised, refer the request to the regional privacy advisory group, refer the request to the regional clinical information services leadership group or deny the request. Where a request for response to queries raised is required, any responses received will only be reviewed at a subsequent regional éclair management group meeting. Where a request has been denied, an explanation as to why the request was denied will be provided.

Additional consideration

Ethical review

Changes to the Health and Disability Ethics Committee (HDEC) review process in July 2012 means that some research previously requiring ethical review are no longer reviewed by this process. In addition, the inclusion of screening questions on their online application form has caused some confusion as to what type of study does and does not require ethical review.
For the purposes of access to testsafe data, any application will require ethical review via the HDEC.
In cases where the applicant is an employee of a New Zealand university, where HDEC review is not required, the applicant must obtain ethical approval via their university ethical review process.

Locality approval

In addition to ethical review, DHBs and other organisations will have their own locality approval that must be obtained before submitting the request for the data. HDEC have confirmed that, for the purposes of data requests to testsafe, the lead investigators employing organisation is the locality, not testsafe.

Data management

Applications should describe every field in the proposed data, the associated risk of re-identification, and if this risk is substantial and can't be mitigated, why the field is absolutely required for analysis.
An example of datum that (in association) easily permits re-identification is the patient's date of

birth – provision of just the year of birth instead should minimally influence the quality of the data analysis, but may substantially decrease the risk of re-identification. No unencrypted NHI data will be provided. If NHI data is required, the researchers must consult an expert at cryptography and provide the advice for review. Applicants must also provide a clear explanation as to how the data will be accessed and will be protected to ensure patient confidentiality and is consistent with DHB and testsafe's privacy framework and the Health Information Privacy Code.