Accessing testsafe data for audit, evaluation and research

Guidelines to applicants

Introduction

Testsafe is a central repository of diagnostic level information for the northern region DHBs (Northland, Waitemata, Auckland and Counties Manukau) and is operated by healthAlliance. It's Raison d'être is to provide a patient centric view of the regional data for DHB and primary care clinicians.

Applicants with existing access to testsafe data for clinical purposes are not authorised to use their access for the purposes of research, audit or evaluation. This rule applies even when approval to access testsafe data for the purpose of research, audit or evaluation has been provided by the Regional Éclair Management Group.

Making an application to access testsafe data

To request access to testsafe data for the purposes of research, audit or evaluation applicants must provide the Regional Éclair Management Group with, at the minimum, the particular information outlined below to enable the group to review the applications. There is no specific form or template applicants need to use however each of the headings below must be addressed in the application – failure to do so will result in your application being returned unassessed.

All applications must be submitted to the healthAlliance CareConnect Manager by the last working week of each month, for inclusion in the next scheduled meeting.

Information required

Please provide the following information in your application

Heading	Questions that need to be addressed
Source data	As a first principle the data should be sourced from the primary source. Therefor testsafe as a regional repository is not the source systems. You must provide a strong justification as to why the data is only available within testsafe.
General information	Who is requesting the access? • Provide details of who the lead investigator is, including contact details, their role and the organisation they work for. • Provide details of any co-investigators also involved in the study. • Specify any conflict of interest – real or apparent.
Background and significance	Why is your proposal important? • State the problem your proposal will address and how it will contribute to current knowledge • Summarise the existing evidence
Aims and hypotheses	What is the purpose of your proposal • Outline the aims/objectives of your research of the hypotheses you are addressing. • Where appropriate identify primary objectives and secondary objectives
Methodology *Study design* *Participants*	What is the study design? • Describe the proposed study design Who is the population being studied? • Specify who the sample population is. Include details of inclusion or exclusion criteria

Data collection	• Describe the sampling framework or sample size calculations • If a control group is being used, define the matching criteria What data is being collected • 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. • If NHI data is required, the researches must consult an expert at cryptography and provide the advice for review. • Provide any consent to obtain data that you have • Provide details of any other variables being collected and from what sources the data is being obtained • Include details of any methods for data checking or cleaning that might be used.
Ethical considerations	What are the ethical issues for the proposal? • Provide detail of any ethical concerns the proposal raises and how these will be addressed? • If ethical review is being sought via the Health and Disability Ethics Committee or an institutional ethics committee provide details of whom and current status of the application • If ethical review is not being sought, provide the peer reviewed rationale
Confidentiality	How will data confidentiality be ensured? • Describe how data will be stored and what protections will be in place to ensure confidentiality? • Include what will happen to the data once the research is complete
Reviews and approvals	Has the proposal been reviewed or approved? • If applicable provide details of any peer review of the proposal and include them with your application • Provide details of any other approvals obtained
Timeline	How long will access be required? • Provide details of the proposed timeline for the proposal including timeframe for data collection, analysis and write up.
Use and dissemination	How will the findings be used? • Outline the likely outputs from the proposal and how the findings will be used. • Include any plans for dissemination – conference presentation, journal publications
Funding	Provide details of how you will cover the costs for data retrieval through testsafe.

Possible Decisions

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.

Amendment to proposal

The lead investigator should notify the CareConnect manager in writing of any amendment to the proposal which has implications for the data accessed through testsafe. Any additional data will need to pass through the same approval process

Completion of the proposal

It is the lead investigator's responsibility to notify the Regional Éclair Management Group on completion of the study.

Other approvals

Approval to access testsafe data from the Regional Éclair Management Group does not constitute ethical approval or DHB locality approval. It is the responsibility of the lead investigator to ensure they have obtained any other relevant approvals and that these are submitted to the CareConnect manager. Any request for data extraction will not be processed until all appropriate approvals have been received by the CareConnect manager.

Ethical approvals

Ethical approval via the Health and Disability Ethics Committee (HDEC) may be required for a proposal to access testsafe data. Further information on what studies may require ethical review and guidance on ethical standards in research are available at:

http://ethics.health.govt.nz/ethical-standards-health-and-disability-research

Information on how to apply for ethical review, including the HDEC online application forms is available at:

https://www.ethicsform.org/nz/SignIn.aspx

For lead investigators employed by a New Zealand University, where ethical review is not required via the HDEC process, ethical review and approval by the university's ethics committee may be required.

Locality review

The lead investigator's employing organisation local requirements for research, audit or evaluation activity that must be complied with and proof of approval must be submitted.

Data management

To ensure compliance with the Health Information Privacy Code (HIPC) and the Privacy act, it is important to ensure that any health data collected is protected against loss, unauthorised access, use, modification, disclosure or other misuse by putting in place effective safeguards.

Further information on how to protect the confidentiality of health information is available in the Health Research Council's *Guidelines on Ethics in Health Research May 2002 (Revised 2005).*

http://www.hrc.govt.nz/sites/default/files/HRC%20Guidelines%20on%20Ethics%20in%20Health%20Research.pdf

Explain fully how you intend to comply with these requirements.