Human Research Ethics Application

Application Management Information
Application ID: 2020/ETH00167
Created date: 24/08/2020
Originating Application ID:
**This is the earliest application from which this application (2020/ETH00167) was copied.*
Parent Application ID:
**This is the immediate predecessor from which this application (2020/ETH00167) was copied.*
Version Number: 1
Application submitted to: Sydney Local Health District; Sydney Local Health District Human Research Ethics Committee - Concord Repatriation General Hospital.

The applicant has requested that this ethics application be considered under the Negligible risk review pathway.

Comment [A1]: Please see the Concord Hospital Research Office website for details of deciding the risk pathway.

Section 1 – Core Information

Pre-application conditions

The applicant/s have acknowledged that:

1. The HREA has been designed for ethics review of human research, as defined in the National Statement.
2. Adequate resources must be available to conduct this research project.
3. All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to.
4. Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.

Project Overview

Q1.1 Project Title:

Retrospective Medical Records Audit

Q1.2 Summary of the research project:

Provide a project summary in non-technical language. This should be a synopsis of the overall project, similar to a research abstract.

Q1.3 Which category/ies of research best describes the project?

Clinical Sciences - 1103

Q1.4 In what environments will the research be conducted?

- Clinic(s)
- Community centre(s)
- Cultural/religious organisation(s)
- **Hospital(s)**
- Online
- Private residence(s)
- Professional organisation(s)

- Public place(s)
- Research institute(s)
- School system(s)
- University(ies)
- Workplace(s)

Q1.5 What organisation/entity has overall responsibility for this project?

Sponsor type: Institution/Investigator-initiated
Sponsor name: Sydney Local Health District

Q1.6 Describe how this research project is currently, or will be, funded.

Describe how this research project is currently, or will be, funded including the amount and source of funding.

Q1.7 Anticipated starting date of the research project:

As soon as ethics and any other relevant approvals have been provided.

Q1.8 Anticipated duration of the research project:

5 Years

Comment [A2]: Ethics approvals are valid for 5 years.
It is recommended researchers follow the guidance for data retention as outlined in the Australian Code for the Responsible Conduct of Research, 2018 (the 2018 Code) - management of data and information in research. In general, the minimum period for retention of research data is 5 years from the date of publication.

Project Team

Name: **Dr Steve Rogers**

Q1.9.4 Email Address:

Steve.Rogers@institutionalemailaddress.gov.au

Q1.9.5 Is this person the contact person for this application?

Yes

Q1.9.5.1 Email Address:	Steve.Rogers@institutionalemailaddress.gov.au
Q1.9.5.2 Telephone Number:	02 9767 6676
Q1.9.5.3 Mailing Address	Hospital Road, Concord Repatriation General Hospital, NSW, 2137

Q1.9.6 Is this person a student on this project?

No

Q1.9.7 Institutional affiliation and position:

Sydney Local Health District

Q1.9.8 Staff ID *(optional)***:**

Q1.9.9 ORCID Identifier *(optional)***:**

Q1.9.10 Position on the research project:

Co-ordinating Principal Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

Yes

Q1.9.12 Research activities Dr Steve Rogers will be responsible for:

Briefly describe the research activities the person will be undertaking in relation to the research project. For example, participant recruitment, obtaining consent, data collection, sample collection or data analysis.
• If this person is responsible for directly supervising students this activity should be recorded here.
• If this person has multiple roles on the project (e.g. both an investigator and supervisor on a university project or both a CPI and PI on a clinical trial) ensure you outline the responsibilities of each role.

Q1.9.13 Expertise relevant to the research activity:

- National Statement 1.1 states:

"Research that has merit is …conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research."
Consider the research activities that this person will be responsible for and explain how their

Comment [A3]: All members of the project team should be listed.

Comment [A4]: For team members who have affiliations outside of the Sydney Local Health District, please clarify if any data will be stored, analysed or shared with <institution> and if so what data?

Comment [A5]: Please note that Coordinating Principal Investigator (CPI) and Principal Investigator (PI) are synonymous for single site studies.

The terms Coordinating Principal Investigator (CPI) and Chief Investigator (CI) are synonymous. The Committee prefers the term CPI and there can only be one CPI for the study.

If one of the researchers is a student, ensure that the student's supervisors are also listed as investigators. It is the Committees preference that students are not the CPI for the study.

The CPI should be listed first in the study team.

Comment [A6]: Q1.9.11 should be answered 'yes' only for the CPI.

qualifications, training, experience, skills, experience, qualifications and competence make them appropriate for their role in the research project.

Disclosure of interests

Q1.10 Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?

No

Comment [A7]: If 'yes' it is suggested that in line with the *National Statement on Ethical Conduct in Human Research (2007 – updated 2018) Chapter 5.4: conflicts of interest,* the researchers are should comment on the potential for conflict of interest <<name>> and <<organisation>>. This information should be included in the PISCF (if applicable).

Restrictions

Q1.11 Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?

No

Evaluations

Q1.12 Has the scientific or academic merit of the research project been evaluated?

No

Q1.13 Has this research project had prior ethics review?

No

Q1.14 Will any further or additional specialised review of this application be sought?

No

Comment [A8]: This should be answered yes if conducting research at public health sites. A Site Specific Assessment (SSA) is required at each site.

Setting of research

Q1.15 Will this project be conducted at multiple sites?

No

Q1.16 Will separate institutional approvals or authorisations be required prior to commencing research at each site?

Yes

Section 2 – Research Details and Participants

Q1.17 The following research methods will be used in the research project:

Research Method	Status
Action research	✗
Biospecimen analysis research	✗
Data linkage research	✓
Ethnographic research	✗
Epidemiological research	✗
Interventional/Clinical Trials research	✗
Observational research	✓
Survey/Interview/Focus Group research	✗
Textual analysis research	✗
None of the above	✗

Comment [A9]: Depending on the sources of data, 'data linkage research' may or may not be applicable.

Comment [A10]: For a retrospective medical record review please select 'Observational research' and answer corresponding questions.

Q1.18 The research will be conducted with the following:

Participation	Status
Human beings (via active participation), including their associated biospecimens and/or data.	✗
Human biospecimens only	✗
Data associated with human beings only (i.e. as the primary object of research)	✓

Q1.18.1 Does your research involve the prospective collection of data?

No

Q1.19 The research will involve the following participants:

Participants	Status
Women who are pregnant and the human fetus	✗
Children and young people	✗
People highly dependent on medical care who may be unable to give consent	✗
People with a cognitive impairment, intellectual disability or mental illness	✗
People in dependent or unequal relationships	✗
People who may be involved in illegal activities	✗
People in other countries	✗
Aboriginal and Torres Strait Islander peoples	✗

Method Specific Questions

Data Linkage Research

M3.1 How will your research/findings account for any limitations arising from your choice of data sets/databases or from missing data?

• Refer to any relevant sections of the Project Description/Protocol.

M3.2 How will you control for confounding factors or other vulnerabilities toward bias in your research?

• Refer to any relevant sections of the Project Description/Protocol.

M3.3 How will you manage any risk that linking databases of non-identifiable data could subsequently result in the individuals being identified?

• Consider the Australian National Data Service Publishing and Sharing Sensitive Data Guide.

Observational Research

M7.1 What type of observation will you be conducting?

Details of the method that will be used should be included in the Project Description.

Please include this information in the protocol.

M7.2 What sampling strategy will you use?

Description of the sampling strategy and justification for this strategy should be described here.

Please include this information in the protocol.

M7.3 How will you match and follow up participants?

A full description of how participants will be matched and followed-up should be described.
Include justification for following up participants and the timepoints.
If matching and following up will not occur, please stipulate here and in the protocol.

Please include this information in the protocol.

M7.4 How will potential sources of bias be addressed, including consideration of both the direction and magnitude of bias?

Sources of bias (including information bias and selection bias) and mitigation strategies should be described, including how these bias' may create limitations in the study design and that these limitation will be acknowledged in any publications.

Please include this information in the protocol.

Participant Specific Questions

Recruitment Questions

As the research involves *Data associated with human beings only*, no recruitment questions were asked. Any issues related to access to the data and consent to its use initially in the Consent Section and Data and Privacy Section

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Consent Questions

Q2.2.5 Has consent been obtained from participant for the use of their data in the proposed research?

No

Q2.2.5.2.1 Explain why consent for use (or secondary use) of the data has not been obtained?

• You may wish to explain whether an opt-out approach or waiver of consent to use of the data was approved for this purpose or whether an institutional policy or legislative provision applies.

Comment [A11]: If a waiver of consent is being requested, the response will be 'no'. Otherwise, if consent will be obtained from participants please include a Participant Information Sheet and Consent Form with the application.
If using data for research purposes you either need to obtain consent from the individual or request a waiver of consent for the secondary use of data under the Privacy Act. If a waiver of consent is being requested, the response will be 'no'. Otherwise, if consent will be obtained from participants please include a Participant Information Sheet and Consent Form with the application
Please see section 2.3.10 of the National Statement on Ethical Conduct in Human Research (2007) – updated 2018 for the criterion in which an application for a waiver of consent will be assessed. This information should be included in the protocol.
The template can be found on the CRGH Research Office website.

Risk Questions

Q 2.3.1 Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description as appropriate.

Please acknowledge any risk to patient privacy and confidentiality, even if minimal. Other risks and burdens may include: Physical harm, Psychological harm, Disclosure of sensitive personal information, Exposure of illegal activity, Economic harm, Discrimination, stigma or other social harm / Devaluation or harassment / Familial distress / Harm to any member of a vulnerable population / Reputational harm.

- Consider whether your research is likely to result in discomfort or inconvenience and how this might occur.
- Include risks to and burdens on participants, researchers and third parties (individuals or groups).
- Consider the multiple levels of personal relationships that may arise during research (especially in ethnographic research or research using the participant-observation or other observational methods) and their impact upon participants, researchers and third parties.
- Consider whether there are any concerns that might be relevant to the research project regarding political or institutional sensitivities.
- Consider whether any combination of methods being used in this research might lead to additional risks.

Please include this information in the protocol.

Q 2.3.2 Describe how these risks will be mitigated and managed.

Section 2: Themes in research ethics: Risk and benefits, consent, of the National Statement on Ethical Conduct in Human Research (2007) - updated 2018 should be considered in this response.

Please include this information in the protocol.

Benefit Questions

Q2.4.1 Describe the benefits associated with your research, referencing any relevant sections of your Project Description as appropriate.

• You will be asked about any ethical considerations associated with the benefits of your research project in this section. Where this is already considered and provided in the Project Description/Protocol, this should be cross referenced in the application.
• Include benefits, if any, to participants, to groups and communities, to society, to the advancement of knowledge and to researchers.
• Include any benefits accruing from the possible availability of the intervention after completion of the project.

Section 2: Themes in research ethics: Risk and benefits, consent, of the National Statement on Ethical Conduct in Human Research (2007) - updated 2018 should be considered in this response.

Please include this information in the protocol.

Q2.4.2 Explain how benefits of this research justify any risks or burdens associated with the research.

Section 2: Themes in research ethics: Risk and benefits, consent - Do the benefits justify the risks of the National Statement on Ethical Conduct in Human Research (2007) - updated 2018 should be considered in this response.

Please include this information in the protocol.

Q2.4.3 How will you manage participants' expectations of the perceived benefit of participating in the research?

• Consider both expectations of benefits that are not likely to eventuate and expectations of benefits that can reasonably be expected to eventuate, but where there may be a misperception as to the extent of those benefits. For example, therapeutic misconception in clinical research.

Section 2: Themes in research ethics: Risk and benefits, consent - Do the benefits justify the risks? of the National Statement on Ethical Conduct in Human Research (2007) - updated 2018 should be considered in this response.

Please include this information in the protocol.

Section 3 – Data and Privacy

Data Characteristics

Q3.1 Indicate the type of information/data you will be collecting for this project.

- Personal information
- Sensitive information
- Health information
- Not personal information

Q3.2 Indicate the type of information/data you will be using in this project:

- Personal information
- Sensitive information
- Health information
- Not personal information

Q3.3 Indicate the degree of identifiability of information/data you will be collecting for this project.

- Individually identifiable information
- Re-identifiable (coded) information
- Non-identifiable information

Q3.4 Indicate the degree of identifiability of information/data you will be using in this project.

- Individually identifiable information
- Re-identifiable (coded) information
- Non-identifiable information

Q3.5 Describe any ethical considerations relating to the collection and/or use of the information/data in this project.

• Consider and refer to Element 4 of the National Statement on Ethical Conduct in Human Research (2007) - updated 2018 Chapter 3.1. Please also consider the ethical principles of autonomy, justice, non-maleficence and respect in the response.
• Refer as necessary to the type and/or degree of identifiability of the information.
• In your response describe what personal identifiers will be retained or, if removed, how and at what stage in the project.
• Detailed information regarding the ways in which data will be collected and/or used should be included in the Project Description/Protocol. You may wish to provide reference to the relevant sections of the Project Description/Protocol in your response, if appropriate.
• Your response should include any ethical considerations that relate specifically to the proposed approach/es to collection and/or use of project information/data and the nature of the information/data.
• Note that some issues, such as recruitment and consent, are addressed in other sections of this form.
• Include any conditions imposed by a third party on your access to pre-existing data, for example that you will share the results with the data custodian.
• Consider whether it may be possible for information that is collected/gathered/ accessed for this project to be converted into health information as a function of how it is used and analysed during the research project.

Please also list all of the data variables which will be collected in the study.

Comment [A12]: Personal information is defined in the Privacy Act 1988 as information or an opinion about an identified individual, or an individual who is reasonably identifiable:
・ Whether the information or opinion is true or not; and
・ Whether the information or opinion is recorded in a material form or not.

Comment [A13]: Sensitive information is defined in the Privacy Act 1988 as:
- information or an opinion about an individual's:
  - racial or ethnic origin; or
  - political opinions; or
  - membership of a political association; or
  - religious beliefs or affiliations; or
  - philosophical beliefs; or
  - membership of a professional or trade association; or
  - membership of a trade union; or
  - sexual orientation or practices; or
  - criminal record; that is also personal information; or
  - health information about an individual; or
  - genetic information about an individual that is not otherwise health information; or
- biometric information that is to be used for the purpose of automated biometric verification or biometric identification; or

biometric templates

Comment [A14]: Health information is defined in the Privacy Act 1988 as:
- information or an opinion about:
- the health, including an illness, disability or injury, (at any time) of an individual; or
- an individual's expressed wishes about the future provision of health services to the individual; or
- a health service provided, or to be provided, to an individual; that is also personal information;
- other personal information collected to provide, or in providing, a health service to an individual; ...

Comment [A15]: Usually individually identifiable information will be collected initially, unless data is sourced from an anonymous dataset.

Comment [A16]: Unless using a completely anonymised data set, most research will collect, use and store re-identifiable (coded) information. Data should be kept in re-identifiable form (for auditing and monitoring purposes) for the requisite time. Please revise.

Please include this information in the protocol.

Q3.6 Identify the source/s of the information/data that you will be collecting and/or using in this project.

Medical/health/mental health record

Q3.6.1 Has the data custodian/s, if any, agreed to provide access to the data for use in the proposed research?

Data custodian has approved access to data

Comment [A17]: If answered 'yes' please provide approval letter/support.

Q3.7 Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question.

• Consider whether the information about an individual will be sought from the individual themselves or via a third-party.
• Consider whether the information will be gathered from medical/health/mental health record or from the records of a law enforcement agency. Consideration should also be given to the consent mechanisms that must accompany requests for such information. Consent may be needed both from the participant and from the agency holding the records.

Element 4: Collection, use and management of Data and information of the National Statement on Ethical Conduct in Human Research (2007) - updated 2018 8 should be considered in this response.

Please include this information in the protocol.

Q3.8 Was the information/data that you are using previously collected for a purpose other than research?

Yes

Comment [A18]: Usually the information/data was previously collected for clinical purposes.

Q3.8.1 Provide a rationale for your use of information/data for a purpose other than that for which it was originally collected.

• Consider the source/s of your data and the reason/s for which it was originally collected. In most instances, the information/data was previously collected for clinical purposes.

Please include this information in the protocol.

Activities Planned for/with Data

Comment [A19]: A Research Data Management Plan (RDMP) should be provided as a separate document for review and approval. Please see the CRGH Research Office website for the template. Note, for all enquiries regarding completing the RDMP, please contact the SLHD Research Data Manager can be contacted for assistance and bookings via email or online for consultation if necessary.

Q3.9 Do you plan to disclose any personal information/data in this project to a third party?

No

Q3.10 How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research?

• "Notes" include field notes.
• Describe the strategy you will adopt regarding identifiability, coding or de-identification of information.
• Include whether or not you plan to disclose any information obtained from participants.

• This issue is of particular relevance for survey-based, ethnographic and observational research but may also be pertinent for other research.

Element 6: Dissemination of project outputs and outcomes the National Statement on Ethical Conduct in Human Research (2007) - updated 2018 should be considered in this response.

Please include this information in the protocol.

Q3.11 Are there any restrictions on your ability to assure the confidentiality of participants?

No

Q3.12 Do you plan to share any individual research results obtained during this research to the participants?

No

Q3.13 Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data.

• Where relevant, you may need to distinguish between obligations attached to clinical care and research and between findings that are both analytically valid and clinically actionable and those that are not.
• Consider, where relevant, findings related to human genomics, imaging and non-medical research.

Element 6: Dissemination of project outputs and outcomes the National Statement on Ethical Conduct in Human Research (2007) - updated 2018 should be considered in this repsonse.

Q3.14 Describe how the information/data will be stored, accessed, archived and/or destroyed.

• Cross reference relevant sections of the Project Description/Protocol if applicable.
• Note that institutions may also have internal policies that have an impact upon data storage and access.

Please include a Research Data Management Plan with the application. The template can be found on the Concord Repatriation General Hospital Research Office website under Forms and Templates.

Please include this information in the protocol and RDMP.

Responses to this section should also be included in the protocol and RDMP.

Q3.15 Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.

Please include the response to this question in the protocol and RDMP.

Please include reference to the use of the principles outlined in the NHRMC *Australian Code for the Responsible Conduct of Research, 2018 (the 2018 Code*), specifically, the Management of Data and Information in Research

Q3.16 Will the outcomes of this project be disseminated to the participants?

No

Comment [A20]: For best practice data storage and management, it is recommended that the SLHD software licence for REDCap (Research Electronic Data Capture) should be used to capture and store research data as this is a secure web-based data management tool designed for research purposes:
- •REDCap is available via the following link: https://redcap.sswahs.nsw.gov.au/
- •Training videos and resources are available via the following link: https://redcap.sswahs.nsw.gov.au/index.php?action=training
- •The SLHD Research Data Manager and REDCap Administrator can be contacted for assistance and bookings via email or online for consultation if necessary.
- •Please note, one of the benefits of REDCap is, the Master Code Sheet Project Template within REDCap which can be used for storage of identifiable patient data which will auto generate a de-identified record within a separate research data project in the REDCap system using a "Record ID" as a participant identifier.
- •The SLHD Research Data Manager can be contacted for assistance and bookings via email or online for consultation if necessary.
- •Use of Excel is not recommended for secure and safe data management. For best practice data storage and management, it is recommended that the SLHD software licence for REDCap (Research Electronic Data Capture) should be used to capture and store research data as this is a secure web-based data management tool designed for research purposes and can be used to securely transfer data if required.

Q3.16.2.1 Justify why the outcomes of this project will not be disseminated to the participants.

• National Statement on Ethical Conduct in Human Research (2007) - updated 2018 section 1.3 (d) states:
"Research that is conducted with integrity is carried out by researchers with a commitment to: disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding".
• Outcomes means of research other than individual test results or findings related to specific participants that are returnable.
Please also consider Element 6: Dissemination of project outputs and outcomes the National Statement on Ethical Conduct in Human Research (2007) - updated 2018 in this response.
Please include this information in the protocol.

Q3.17 Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.

• Future use may include sharing information with other researchers, secondary use of information for related research, publishing the data for unrelated research and non-research purposes and other possible uses.
• Include in your response any limitations on future use.
• Include in your response any expectations or requirements by funders, publishers or others to make data available.
• Consider the Open Access policies of NHMRC and ARC.

Please include this information in the protocol and RDMP.

Q3.18 Describe any ethical considerations relating to the planned or possible future use of information/data in this project.

• Consider whether non-identifiable data could be used in future research.
• Consider the ARDC Publishing and Sharing Sensitive Data Guide.
• Ethical considerations may include your potential obligations to act on the findings of your research in the future.
• Consider who will have ongoing custody of data or research outputs, including any intellectual property ownership.
• If data will be made available for any purpose, describe how the approach will protect participant privacy. See the ARDC Publishing and Sharing Sensitive Data Guide.
• Consider whether appropriate consent for the future use of data has been sought.

Please include this information in the protocol and RDMP.

Section 4 – Attachments and Declarations

Attachments

The following documents have been attached to this HREA.

Project Description/Protocol

Protocol Template.doc.doc
SLHD Privacy Compliance Form.doc
Research Data management Plan.doc
Master Code Sheet.doc
Data Collection Form. doc

Other attachments

Attachment File Name	Attachment Description
Project Registration	The output from form the Project Registration

Investigator Team Declarations

The research team has certified that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Dr Steve Rogers
☑Certified

Comment [A21]: Declaration and application submission must be by the Co-ordinating Principal Investigator.