WESTERN SYDNEY LOCAL HEALTH DISTRICT (WSLHD)

RESEARCH OFFICE

HREC POSITION DOCUMENT
FOR RESEARCHERS

September 2019

<table>
<thead>
<tr>
<th>Date</th>
<th>Rev No</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>16.09.19</td>
<td>1</td>
<td>Kellie Hansen, Manager, Research Office</td>
</tr>
</tbody>
</table>
Contents
PURPOSE .......................................................................................................................... 3
ABORIGINAL HEALTH AND MEDICAL RESEARCH COUNCIL (AHMRC) ........................................ 3
COMPENSATION FOR STUDY PARTICIPATION ........................................................................ 3
CONSENT .................................................................................................................................. 4
   PARTICIPANT INFORMATION AND CONSENT FORMS ................................................................. 4
   CONSENT TO APPROACH ........................................................................................................... 4
   OPT-OUT CONSENT ..................................................................................................................... 4
   WAIVER OF CONSENT ............................................................................................................... 4
   WITNESS TO CONSENT ............................................................................................................. 5
COORDINATING PRINCIPAL INVESTIGATOR (CPI) / PRINCIPAL INVESTIGATOR (PI) ........... 5
DATA COLLECTION .................................................................................................................... 5
GUARDIANSHIP .......................................................................................................................... 6
IDENTIFIABLE DATA ..................................................................................................................... 6
INTERPRETERS ........................................................................................................................... 8
MEMORANDUM OF UNDERSTANDING (MoU) ............................................................................ 8
PAEDIATRIC RESEARCH ............................................................................................................ 8
RETROSPECTIVE APPROVAL ....................................................................................................... 9
TRANSCRIPTION OF INTERVIEWS / FOCUS GROUPS .............................................................. 9
PURPOSE

The purpose of this document is to describe the position of the WSLHD HREC under the guidance of the National Statement and other guiding documents, however there are circumstances when these may vary. Several items can be addressed in pre-submission discussions with the Research Office, however some items need to be presented to the HREC, are judged on a case by case basis, and must receive approval of the HREC.

ABORIGINAL HEALTH AND MEDICAL RESEARCH COUNCIL (AHMRC)

- The WSLHD HREC is not accredited to review research involving ATSI peoples, that is where ATSI participants are the focus of the research. This type of research must be reviewed by the Aboriginal Health and Medical Research Commission (AH&MRC) Ethics Committee.
- The Ministry states, The AH&MRC Ethics Committee reviews applications from the perspective of the impact on Aboriginal people. The review is required in addition to review by a lead or local HREC.
- Under the NSW Ministry of Health, Office of Health and Medical Research, Policy Directive 055_2010 – research conducted in a public health organisation must also have public health HREC approval.
- The AH&MRC is not on REGIS. Currently they accept submissions via email and will shortly be moving to an online forms system. If Aboriginal and Torres Strait Islander people will be recruited coincidentally the project can be submitted as usual to the WSLHD HREC.


COMPENSATION FOR STUDY PARTICIPATION

- Participant compensation should be reasonable travel expenses only and meals or meal vouchers for extended study visits. Store or movie vouchers should not be offered as these may be viewed as an inducement (National Statement 2.2.10 It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable.)
CONSENT

PARTICIPANT INFORMATION AND CONSENT FORMS

- Written informed consent should be obtained whenever possible, it should be voluntary and based on sufficient information and adequate understanding of the research and the implications of participation.
- When appropriate consent should be renegotiated or confirmed especially for complex, long-running, or phased clinical trials, vulnerable patient groups are or if changed conditions due to safety issues being identified or major changes to the protocol.
- The NHMRC templates should be used.
- If the study is multicentre the Master PICF with no local content should be submitted with the ethics application.
- The PICF should be written in lay language with a target audience of 14 years of age or 8 years of education. If unsure of the reading age of the document there is free readability software available to run the document through; google “free readability software”. A document with lay alternatives of medical terms is available from the research office.
- The PICF does not need to be signed by a witness unless the participant requires a person responsible to sign on their behalf or if an interpreter is used. The person responsible or interpreter cannot be the witness.

CONSENT TO APPROACH

- Researchers must have consent to approach to recruit to their research
- Participants in research should be approached at a usual contact, e.g., at a routine clinic visit, during a hospital admission, or sent with usual correspondence
- An anonymous survey left in a waiting room with a secure drop box is also acceptable, however clerical staff should not be involved in recruiting patients in the clinic
- A letter or email can be sent to patients of the service with either a contact name and number or a link to an anonymous survey. If the patient does not respond a second contact is not permitted. If the patient accesses the link to complete the survey then consent is implied and no PICF or signature is required

OPT-OUT CONSENT

- The WSLHD HREC does not approve opt-out consent. This is included in the National Statement (2.3) as an accepted form of consent in certain circumstances, however, the opt-out approach is unlikely to constitute consent when applying commonwealth privacy legislation to the handling of sensitive information, including health information. The WSLHD HREC position is that a patient should not have to withdraw from being involved in a research project, but rather that the researcher should make contact with the patient, explain their study, and seek their consent.

WAIVER OF CONSENT

- Only an HREC can grant a waiver of consent. The HREC must be satisfied that
- the research carries no more than low risk
- the benefits outweigh the risks
- it is impracticable to obtain consent
- there is no reason to think that participants would not have consented, and
- there is sufficient protection of privacy

WITNESS TO CONSENT

- As described in the International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) if a subject is unable to read or if a legally acceptable representative is unable to assist, an impartial witness should be present during the entire informed consent discussion. Likewise if the participant does not speak English, a healthcare interpreter should be provided to assist the participant in the reading and understanding of the consenting process. After the participant or their representative has signed the consent, the witness should sign and personally date the consent form. By signing and dating the consent form the witness attests that the information in the consent form and any other written information was accurately explained to and apparently understood by the participant and/or their representative, and the consent was freely given. The witness does not have to speak or understand the language used.

COORDINATING PRINCIPAL INVESTIGATOR (CPI) / PRINCIPAL INVESTIGATOR (PI)

- The CPI/PI must be a senior clinician/researcher (Medical, Nursing, Allied Health) employed by WSLHD with authority to oversee the conduct of the study and the right to access the patient group who are the focus of the research. A student, registrar, fellow, or contingent worker cannot be the CPI/PI
- The CPI does not need to be from WSLHD as long as there is a named PI who is a senior clinician with an appointment at WSLHD
- Amending the CPI/PI should be done via REGIS to the lead HREC Research Office. Amendments to other study staff should be done via the local ongoing site authorisation process to the local Research Governance Officer
- Some areas have very few staff who are employed by WSLHD. In this circumstance, a senior clinician/researcher (Medical, Nursing, Allied Health) with a conjoint appointment can be the CPI/PI (e.g. Westmead Centre for Oral Health – WCOH)

DATA COLLECTION

- Study data should only include study code, age, and gender, no identifiable fields should be included e.g. MRN, Name, DoB. The study code should not comprise all or part of any identifiable fields e.g. MRN, DoB, Initials
- A source document should be created, and held separately and securely to the study data, linking the study code to the identifier e.g. 001 = MRN.

190916 - HREC Position document - Researchers.docx
• All study documents should be held on a password protected LHD PC in a locked office only accessible by the research team. No portable devices should be used e.g. USB, laptops etc
• No identifiable data should leave the LHD
• In any study that proposes to collect patient data, the protocol must describe the privacy, retention, storage, security, access and destruction arrangements for the data
• If data linkage is to be used the type of data and identifiability of data must be considered
  o Linkage to state-held data sets requires the ethics application to be submitted to the Population Health HREC at the Cancer Institute. This is the only HREC that can provide approval for the access of data via CHEREL (Centre for Health Record Linkage).
  o If it is intended to link data from two services within the health system (e.g. cardiology and emergency) this application can be submitted via the usual channel, however the protocol must describe the privacy, retention, storage, security, access and destruction arrangements for the data

GUARDIANSHIP

• The Guardianship Division of the NSW Civil and Administrative Tribunal (NCAT) must approve clinical trials which seek to involve a person aged 16 years or older with a decision-making disability. NCAT can only approve a clinical trial if it is satisfied that:
  o Only people who have the condition to be treated will participate
  o Risks are no greater than existing treatment
  o Development of the treatment is such that safety and ethical considerations make it appropriate for the treatment to be available
  o Approval from an ethics committee has been obtained
  o NHMRC guidelines have been complied with
  o Potential benefits are balanced against potential risks
  o Placebo can only be approved if there is no treatment for the condition other than observation, treatment of symptoms and nursing care


IDENTIFIABLE DATA

• No identifiable unit record data can leave the LHD. Unit record data are electronic records of information that relate to the health of an individual, which are held in Local Health District (LHD) or Speciality Health Network (SHN) data collections. (PD2018_001 Disclosure of unit record data by Local Health Districts and Specialty Health Networks for research or contractor services) – this policy is currently under review, however, should be followed until the new policy is released
• Unit Record Data include:
  o Admitted patient data collection (including admitted SNAP, and Mental Health)
  o Emergency department data collection
- Non-admitted (NAP) data collection
- Clinical databases

• The CE or delegate may authorise approval of disclosure of unit record data held by the LHD – this person should not be the data custodian. The conditions that must be met for this type of authorisation are:
  - There must be a legal basis for the disclosure of unit record data
  - The Data Custodian must be satisfied that the proposed uses are reasonable and storage and access arrangements comply with policy and legislation and meet any conditions specified by an HREC
  - Data must be transferred using encryption technologies approved by the Data Custodian
  - Data must be stored in a secure physical and electronic environment that is only accessible by the research team. Data should not be stored on cloud services
  - The Chief Executive or delegate may authorise the disclosure of data collections held by the LHD where the proposal meets the following conditions

• An approval must:
  - describe the Unit Record Data authorised to be disclosed;
  - the person and their position within an Organisation who will be responsible for the Unit Record Data at each external site; and
  - the purpose for which the Unit Record Data are being disclosed.

• The approval may be subject to conditions. Conditions that should be considered are shown below.

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>• The LHD/SHN should be acknowledged in any publication or report that arises from the use of the data.</td>
</tr>
<tr>
<td></td>
<td>• The authority to disclose the data continues until and unless it has been revoked in writing.</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>• A confidentiality undertaking is completed prior to the information being released (see Appendix 1).</td>
</tr>
<tr>
<td>Security</td>
<td>• The data are to be kept in a secure physical and electronic environment that is accessible only by persons directly involved in the project</td>
</tr>
<tr>
<td></td>
<td>• If the Principal Investigator becomes aware of any actual or possible breach in data security they must notify all relevant Data Custodians within 48 hours.</td>
</tr>
<tr>
<td>Limit on data matching</td>
<td>• The Unit Record Data will not be matched with information on individuals from another source</td>
</tr>
</tbody>
</table>
Limit on release of Personal Information

- No information is to be released with which it may be possible to identify an individual person.
- Individuals identified in the Unit Record Data are not to be personally identified in any publication or report.

Knowledge translation and preparedness for media interest

- A copy of any publication or report is provided to the LHD/SHN at least two weeks prior to public release.

Deletion/destruction of data

- The data are to be destroyed after [specify number] years

Conditions of HREC approval

- The project is carried out in accordance with the approved ethics application and all subsequent amendments. HREC approval provides the lawful basis for Disclosure and therefore determines what the data can be used for.
- The data will not be matched with information on individuals from another source other than the datasets specified in the approved ethics application.

INTERPRETERS

- Health care interpreters should be used for all research involving LOTE participants. Relatives and friends should not be used to interpret regardless of the review pathway of the project e.g. greater than low risk (clinical trial) or low risk (survey)
- If patient-facing documentation is to be translated into other languages the English version of the document should be presented to the HREC with the ethics submission, no translation certificate is required

MEMORANDUM OF UNDERSTANDING (MoU)

- Ethics review and approval can be undertaken for a private organisation however a MoU must be established between the WLSHD and the private entity.
- When the project is submitted the researcher should provide the Registered Business name and address, ABN, and the name of a person with authority to sign on behalf of the entity.
- The Research Office will establish the documentation and forward to the private entity to sign and return to the Research Office for sign off by the CE Delegate

PAEDIATRIC RESEARCH
• The WSLHD HREC is not accredited to review research involving paediatric participants (0-18 years). Those wishing to research paediatric participants should contact the SCHN Research Office or other certified HREC who is accredited to review paediatric research. The SCHN HREC is accredited to review research for paediatric and adult participants. If the project involves adult and paediatric participants the SCHN HREC can review the entire project.

• If the study is looking at routinely collected data only e.g. QA or if the participant is the pregnant mother not the infant then the WSLHD HREC can review the project.

RETROSPECTIVE APPROVAL

• The WSLHD HREC does not grant retrospective approval for studies completed without first seeking ethics approval. The researcher should consider the likelihood of discovering publishable data before commencing their project.

TRANSCRIPTION OF INTERVIEWS / FOCUS GROUPS

• If a private transcription service is to be used to transcribe interviews or focus groups (written or recorded) a confidentiality disclosure agreement (CDA) signed by the private service should be provided with the application and this should be declared and the service named in the PICF and protocol.