Research and patient confidentiality

Researchers within Southern Adelaide Local Health Network are required to ensure their research pre-screening and recruitment processes are compliant with the Health Care Act 2008, Mental Health Act 2009 and SA Information Privacy Principles.

When a researcher is not part of the team directly caring for the patient, there is no legal authority for those researchers (or anyone acting on their behalf of those researchers) to access a patient’s medical records without appropriate consent in order to identify potential participants for clinical trials or other research projects.

In summary, unless the initial screening for suitability for research is undertaken by someone who is responsible for the patient’s care (or part of the care team), then it may infringe on the Health Care Act 2008 or the Mental Health Act 2009.

Management of pre-screening and recruitment:

Who can approach patients?

Patients can be approached by staff directly involved in their care, and by the research team detailed in the approved ethics application.

Is verbal consent sufficient to approach potential participant?

Yes, verbal consent is appropriate provided this approach has been documented in the ethics application and approved by the SAC HREC. The verbal consent should also be documented in a referral form or in patient paper notes/electronic records.

How should verbal consent be documented?

It would be advisable for the person obtaining the verbal consent to document this in a referral form. This can be a simple form with the study title, person’s name and contact details.

The form should also have a statement: *I have obtained verbal consent from the potential participant, who has agreed to be contacted by the Research team regarding this research project.* This should be signed and dated and the completed form provided to the research team.

How does this relate to the People in dependant or unequal relationships under National Statement Chapter 4.3?

In many cases, the researcher will also be a clinician and have a pre-existing relationship with a patient who is in their care. It is appropriate for the treating clinician to discuss the research project and answer any questions. To avoid the patient feeling pressured to consent participate in the research, it is advisable:

- for the patient to be given enough time to discuss their participation with someone who is able to support them in making their decision i.e. family member, friend, GP or spiritual counsellor
- that the patient’s consent should be taken by an independent person, such as the research nurse or investigator listed in the application that is not directly involved in the patient’s care.
Is a delegation from Head of Department adequate to be recognised as “part of the care team”?

No, a Head of Department cannot delegate someone as part of the care team if they not already. They can confirm arrangements in place for the person being involved with the patient for research purposes.

The ethics application should clearly state the roles and responsibilities for who is “part of the care team” i.e.

- Nurses
- Medical or PhD student
- Research coordinators
- Data team

Can university students recruit patients?

Yes, students may recruit a patient, but they must be supervised at all times and be familiar with the National Statement chapters 2.2. 3.1.8 and 4.3.

The recruitment plan must have HREC approval and governance authorisation.

Can university students gain access to OACIS for Research?

No, students cannot access OACIS exclusively for research purposes. Research is not a pathway to establish access to OACIS or other SA Health eHealth systems.

If a student already has clinical access to OACIS from a department through their clinical placement, and they sign a non-SALHN confidentiality deed, they can access OACIS for research purposes if such access is related to an approved research project.

What if I have a currently approved research project?

If you have a currently approved ethics application with the SAC HREC, you will need to check the pre-screening and recruitment method to ensure it is compliant with the Health Care Act 2008 or apply for an exemption under section 93(3)(f).

(f) disclosing information for medical or social research purposes if the research methodology had been approved by an ethics committee and there is no reason to believe that the disclosure would be contrary to the person’s best interests.

Compliant methods:

- The treating clinician or care team advise a patient during a clinical appointment of a research study that they may be interested in, and gain consent for the researchers to contact them to discuss the study further.
- The treating clinician or care team has already gained informed consent from the patient to access their medical records for research purposes.
  - This can be achieved by clinics providing patients with an information sheet about research / clinical trials. Patients can sign the information sheet and provide informed consent for their medical records to be accessed for research purposes or to be contacted regarding relevant research projects. This informed consent can be recorded in their medical records.
- The direct approach of patients is detailed in the approved ethics application and specifically states who will approach the patients.
- Using the Health Care Act 2008 exemption 93(3)(f) – the ethics application needs to reference this exception and state that in order to identify potential participants for research purposes, the Clinical Trial Coordinator will need to access patient medical records prior to obtaining consent from the patient.

Non-compliant methods

- Accessing medical records without patient consent, to pre-screen for their suitability in any research projects and researchers have not applied for, or had approved, the exemption via the ethics application, or do not have any HREC
approval in place.

- Approaching patient’s directly on wards or in clinics, without this being specifically detailed in the ethics application and approved by the SAC HREC.
- Accessing patient medical records without patient consent and sending out an invitation letter regarding a research project, without HREC approval.

**How do I bring my SAC HREC ethics application into alignment with the policy?**

**Current applications**

If you have reviewed your pre-screening method and it does not comply with the *Health Care Act 2008* or exemption section 93(3)(f), you will need to submit an amendment.

If you are unable to change the pre-screening method to the first two dot points under the compliant methods, please follow the below.

The Coordinating principal investigator will need to submit the Patient Confidentiality and Recruitment for Research Project Amendment Form to the SAC HREC. This amendment will request a waiver of consent, under the National Statement 2.3.10 a, b, d, e, f, i. to access patient’s medical records to pre-screen for research purposes, prior to obtaining consent from the patient.

The form will need to detail the pre-screening methodology, who will access the medical records, and which records are being accessed i.e. EPAS, OASIS.

**New applications**

For new ethics applications, the pre-screening methodology needs to be clearly stated, so it can be appropriately reviewed and approved by the SAC HREC.

Where the initial screening of patients for the suitability for research does not comply with the *Health Care Act 2008*, the HREC may approve the pre-screening methodology, providing it is explicitly described in the ethics application, under s93(3)(f) of the Health Care Act.

The recruitment section will need to contain the below statement to apply for the exemption:

Under s93(3),(f) of the *Health Care Act 2008*, we wish to apply for an exemption of patient consent to access their personal information for research purposes. In order to identify suitable participants for this research project, <specify who or a title i.e. study coordinator> will be required to access <specify what is being accessed>, prior to obtaining consent from the patient.

**How do I bring my SSA only applications into alignment?**

If you have reviewed your pre-screening method and it does not comply with the Health Care Act 2008 or exemption section 93(3)(f), please contact the Officer for Research to discuss the process of contacting the approving Human Research Ethics Committee.

**Resources:**

- [South Australia Health Care Act 2008](http://www.ausgoal.gov.au/creative-commons)
- [Office for Research website](http://www.ausgoal.gov.au/creative-commons)

**Further information**

Please contact the Officer for Research:

8204 6453 / Health:SALHNofficeforresearch@sa.gov.au