Fact Sheet

SCHN Research Ethics and Research Governance

Heads of Departments

Department Heads at SCHN should be aware of all research approved and conducted in their departments, and should ensure that only approved research is conducted according to approval conditions, and relevant national, state and institutional Statements, Guidelines and Policies.

Department Heads have the discretion to declare support for Research Ethics and Governance applications, or to withhold endorsement when they feel their Department is not able to contribute safely, efficiently or effectively to the research endeavor, bearing in mind the existing and other promised responsibilities of the Department.

A consideration process is fundamental in signing off on behalf of your Department on:

Ethics applications
Low or Negligible Risk (LNR) applications
Human Research Ethics Applications (HREA) Forms

Governance applications
Site Specific Applications
Research Governance Amendment

You may be requested to sign off as:

- Head of Department in which the research is conducted and which employs the Chief/Co-coordinating (CI) or Principal Investigator (PI)
- Head of Supporting Department which makes investigators, patients, staff (as service providers and/or participants), testing and diagnostic equipment, or physical space available
- Head of Department (or their delegate for data management) as the "*Authority for the provision of data*", if you hold Department collated specific information (data and samples) as "owner" or "custodian", which are not held for general use
  Note that when the information is held in PowerChart, Medical Records or Pathology, the responsibility for sign off "for the provision of data" generally lies with head of the Medical Records Department or Pathology, or is a shared responsibility between Departments.

In signing off as Head of Department, your signature means you certify and declare that:

- You have reviewed the complete Ethics / Governance application, you understand the research process proposed to be conducted, including the duration of the project,
- You have discussed the project and its resource implications with the researcher,
- You can commit the resources requested of your Department (staff, data, samples, facilities),
- Your Department staff or students are adequately skilled, trained and experienced to be able to fulfill the planned responsibilities, and appropriate supervision of them is available,
- You consider that the proposed research will not overly impede the investigator's other current responsibilities, such as in other research or clinical service delivery,
- You consider that the research will not unduly burden your Department, or impede your Department's other responsibilities, bearing in mind the practicalities of the study design (single-blind/double-blind; phased recruitment and/or treatment, cohort or longitudinall), and

thinking about when participant recruitment occurs and other practical service delivery objectives which may coincide, for instance in clinics, and

- Your planned project will be conducted in an ethical manner and has scientific merit.

Particular issues for multi-centre projects include:

- Can your Department bear the burden of being the coordinating Centre for the project?
- Can your Department receive data/samples from other sites and store it in accordance with National Statement on Ethical Conduct in Human Research and NSW requirements?
- Are you happy for information/samples collected by your department to be released to another organisation/institution (and in what format)?

Your signature is documentation that you have undertaken this process of consideration.

Privacy tips

You should give due regard to any conditions imposed by a Human Research Ethics Committee, and always bear in mind the privacy implications of agreeing to re ease information in a certain form to an investigator.

In general, release of identifiable information for a purpose for which it was not initially collected should only be with the consent of the person identified for its further disclosure or use, or else have the specific approval of the HREC, if they consider the public interest in the research substantially outweighs the public interest in maintaining privacy.

Conflicts of interest which preclude you from signing as Head of Department

You may not sign off on a project which presents a conflict of interest for you as an individual.

Examples of a conflict of interest for you as a Head of Department include:

- When you are also a researcher named in the project
- When you are a consultant for or employee of the (industry) sponsor of the study

Sign off when in potential conflict of interest or in the absence of a Head of Department

If you are on leave, absent from your normal duties, or face a potential conflict of interest, the Head of Department sign off responsibility can be assumed by another employee of the institution who has formally been appointed as:

- Deputy Head or co-Head of your Department, with authority to 'act' in your role, or
- Your Line manager – the person you directly report to, which is often a program chair.

You may not informally delegate this responsibility to others within your Department.

The substitute's sign off will be considered as valid as your own. If you are not comfortable with certain projects being signed off in your absence, you can withhold Departmental sign off authority from those 'acting' in your absence. However, please note that the Ethics and Governance Support Team will not be aware of this arrangement unless we are informed of it in writing.

PLEASE NOTE:

Once the Ethics and Governance Support Teams receive an application form with your signature we will assume that your signature is an endorsement of the proposal.