

# AUSTRALIAN NATIONAL ENDOMETRIAL CANCER STUDY: Policies and Procedures for Access to Data & Biological Specimens and Publication

## ACCESS POLICY

### **Criteria for access to ANECS data and/or biospecimens**

During the data and sample collection phase of the Study and the first 12 months following this period, equating roughly to the period funded by the NHMRC, it is anticipated that access to the ANECS resource will be restricted to projects outlined in the parent grant application. This is to ensure that these original aims can be completed in a timely fashion with no competition for resources.

The only exception will be projects for which additional funding is sought to directly extend the aims of the parent project and so add to the resource e.g. additional funding for mutation detection, which would require access to archival tumour and DNA specimens.

The resource will thus be open to other projects from approximately July 2008. After this time, investigators working in endometrial cancer research may apply to use the resource, with the following provisos:

- Any group requesting access should include at least one ANECS contributor.
- Projects must be peer-reviewed, either by an external funding body, or through ANECS, to ensure scientific validity
- Projects covering the Future Directions outlined in the parent NHMRC application will take priority (See Appendix). These would normally include as chief investigators Amanda Spurdle (AS, for projects involving biospecimens) and/or Penny Webb (PW, projects involving data), in recognition of their intellectual and practical input to the study (>25% time commitment for project set-up and day-to-day running).
- Projects that can *only* be conducted using ANECS resources will take priority, particularly those that make best use of the *multidisciplinary nature* of the resource.
- Projects that have the potential to benefit Australian women will receive priority.
- Projects with investigators who have contributed to tissue collection will be given higher priority for applications requiring use of tissue samples.

### **Procedures for application to ANECS for research project approval**

The steps involved in applying to ANECS for access to biological material and/or data held by ANECS are similar to those used in other large-scale studies. They are as follows:

1. Investigator sends a brief letter of intent (by email) to AS or PW for circulation to the ANECS Working Committee (see Appendix 2 for Committee description). The Committee will discuss the rationale and feasibility of the work and the appropriateness of the ANECS resource for the proposed study. The Committee may also (i) comment on the proposal or (ii) identify other collaborators working in the same area who might like to use/share the same material, either independently of, or in collaboration with, the applicants.
2. If the project is deemed an appropriate use of the resource the investigators will be invited to submit a full proposal (using the ANECS application form available from the ANECS web site), together with the usual ancillary material to the ANECS Committee.
3. Applications and referees reports will be reviewed to assess whether the application comprises a scientifically justifiable, feasible, and high priority use of the material and/or data currently available. (External review may be sought by ANECS for projects without peer-review by a recognised granting agency.) Credit will be given based on the level of contribution (eg. to study design, patient recruitment, sample or data collection, pathology review etc).
4. The Committee may suggest changes to the proposed application and/or options to facilitate communication and collaboration between groups working on similar topics. The applicant may be asked to respond to the reviewers' comments in writing. The final decision will rest with the

Committee. Reasons will be given for refusal of all or part of the proposed use of material. If a proposal is currently under peer review by a granting agency, ANECS can provide a letter stating that the samples requested are available, subject to satisfactory review, confirmation of funding and appropriate ethical approval

5. When a project is approved, the Committee may make conditions on, or restrictions to, use of material or data; suggest mechanisms and timescales for the delivery of the requested samples and/or data; require recovery of the costs involved in preparation of samples or data.
6. On signed and written agreement by the applicant, *and evidence of ethical approval*, the project can proceed according to the agreed protocol. Any significant deviations from the agreed protocol must be sent by the applicants in writing for approval before proceeding.
7. Samples will be shipped and data transferred according to the agreed protocol. Material and data will be supplied as soon as possible after a request is approved and an appropriate MTA signed.
8. Annual progress reports will be required by ANECS, and ANECS reserves the right to withhold the supply of further material and/or withdraw data if the rate of progress and level of reporting is unacceptable.

### **Procedures for application to ANECS for pilot project approval**

Although pilot projects which do not make full use of ANECS resources will not be encouraged, investigators may, with appropriate justification, request permission to conduct a pilot project before submission of a full project application.

In general, a pilot project will involve a limited number (usually < 20) of specimens.

The same processes, application forms and decision criteria will be required as for full applications, except that:

- The need for full peer review will be waived
- Pilot projects will only be approved for one year

The decision to treat an application as a pilot or a full application will rest with the ANECS Committee

### **Responsibilities of investigators who use ANECS material**

The Chief Investigator(s) of the project agree:

1. to discuss authorship of all publications using ANECS resources with the ANECS Committee at an early stage and to acknowledge the ANECS on all publicity related to the project. Investigators will be required to include “The Australian National Endometrial Cancer Study” as an author on all publications using ANECS resources, in addition to any individual ANECS investigators who have contributed appreciably to the work. Investigators are referred to the ANECS PUBLICATION POLICY for further details
2. to obtain and provide proof of clearance for the project for all appropriate institutional ethics committees including, at a minimum, the investigators’ host institution(s) and, if none of the investigators is a QIMR employee, to provide appropriate documentation to allow ANECS to obtain approval for use of the resource from the QIMR HREC
3. to pay for the costs of preparing and shipping biological materials
4. to pay for the costs of extracting or preparing data from the ANECS databases
5. to propose a timeline for the project and to submit annual progress reports. If the project has not been completed within 1 year of the planned completion date, the ANECS Committee reserves the right to terminate the project and recover any outstanding data and biospecimens. All projects will have a maximum 3 year term, after which approval to renew the project needs to be sought by means of a full application.

6. to submit data collected during the project to the ANECS central database according to an agreed schedule and format (e.g. at the time of publication or within 1 year of the end of the study). *The primary responsibility for the ethical and scientifically valid use of ANECS biospecimens and data rests with the Chief Investigators of the individual research projects. However, should problems arise, ANECS reserves the right to initiate confirmatory analyses of materials previously released to researchers for the purposes of quality control. In extreme cases ANECS may ask to review raw data and may institute some review before additional batches of material are given out. Discrepancies will be discussed with the investigators.*
7. to return excess biospecimens to ANECS at the conclusion of the study
8. to sign a Materials Transfer Agreement issued by QIMR
9. to not distribute materials or data to investigators or institutions who are not named in the approved application
10. to not use ANECS data and/or materials for purposes other than those agreed to in the approved protocol
11. if necessary, to inform ANECS of additional investigators involved in the project, and to coordinate additional MTAs to be signed and returned to ANECS management committee for approval
12. to submit draft papers to the ANECS Committee for comment and approval, a minimum of 1 month prior to submitting to a journal for publication

### **Protection of the finite ANECS biospecimens resource**

Because biospecimens are a finite and non-renewable resource (with the exception of cell-lines), every effort should be made to extract the maximum amount of information from each specimen and to avoid duplication of effort. The unique combination of biological samples matched to extensive epidemiological, clinical and molecular genetic data available through ANECS makes this resource particularly valuable. For this reason, priority will be given to projects that utilise this linked information and projects that require access to biological specimens only are unlikely to be approved. In addition, ANECS is unlikely to ship large batches of biological material at one time but will instead ask each applicant to suggest how the material may best be processed. This may include suggestions of batch sizes and milestones by which ANECS can monitor progress – for example, reporting of intermediate results.


## **PUBLICATION POLICY**

- Initial (major) publications that cover the basic aims of the parent grant or rely heavily on biospecimens, will name “The Australian National Endometrial Cancer Study Group” as sole author, with recognition of the contributions of all investigators, clinicians and relevant hospital and project staff noted in a full list of contributors presented as an appendix. (See A. below). Members of the Working Committee will take responsibility for presentation of research results to clinical and other collaborators, at the appropriate forum, to ensure satisfaction of the Vancouver guidelines for publication.
- All subsequent publications arising from use of the ANECS resources will include as author “The Australian National Endometrial Cancer Study Group”, with individual authorship determined by contribution as defined by the NHMRC (and consistent with the Vancouver guidelines), and will acknowledge the contributions of all investigators, clinicians and relevant hospital and project staff as per statement B below.
- Maintaining the reputation and standing of the ANECS resource is critical. AS and PW who manage the parent NHMRC grant and are responsible for the major day-to-day running of the project, therefore have an obligation to ensure the highest standards, consistency and credibility of studies using the ANECS resources. They reserve the right to participate in the preparation, analysis, interpretation, writing and approval of any papers using the ANECS resource, and to be offered individual authorship if their contribution is consistent with the Vancouver Guidelines.
- Publications should include the appropriate statement regarding ethical approval (see C. below).
- Publications should include appropriate acknowledgement of sources of funding (see D. below).
- All publications (and abstracts) should be sent to the ANECS Committee for approval before submission.

### **A. ACKNOWLEDGEMENTS AND AUTHORSHIP LISTING FOR STUDIES WITH ANECS AS SOLE AUTHOR, THAT LIST ANECS COLLABORATORS IN FULL:**

#### **Acknowledgements:**

We would like to thank all the women who participated in the study.

We gratefully acknowledge the cooperation of the following institutions:  *South Wales:* John Hunter Hospital, Liverpool Hospital, Mater Misericordiae Hospital (Sydney), Mater Misericordiae Hospital (Newcastle), Newcastle Private Hospital, North Shore Private Hospital, Royal Hospital for Women, Royal Prince Alfred Hospital, Royal North Shore Hospital, Royal Prince Alfred Hospital, St George Hospital; Westmead Hospital, Westmead Private Hospital; *Queensland:* Brisbane Private Hospital, Mater Misericordiae Hospital, Royal Brisbane and Women’s Hospital, Wesley Hospital; *South Australia:* Burnside Hospital, Calvary Hospital, Flinders Medical Centre, Queen Elizabeth Hospital, Royal Adelaide Hospital; *Tasmania:* Royal Hobart Hospital; Launceston, & North West Regional Hospitals Burnie & Mersey; *Victoria:* Freemasons Hospital, Mercy Hospital for Women; Royal Women’s Hospital; *Western Australia:* King Edward Memorial Hospital, St John of God Hospitals Subiaco & Murdoch.

#### **Appendix: Authorship listing on behalf of ANECS:**

##### ***Queensland Institute of Medical Research:***

*Investigators:* AB Spurdle, P Webb, D Purdie, J Young

*Collaborators:* M Barker, M Walsh

*Project Staff:* S Moore (Project Manager), K Ferguson (Laboratory Manager), B Alexander, L Green, J Hallo, L Jackman, J Maidens, A Marshall, A Mellon, E Minehan; K Nattress, B Ranieri, D Roffe; H Shirley, A Stenlake, S Webb, J White.

***Clinical Collaborators:***

NSW- S Baron-Hay, D Bell, A Brand, S Braye, A Bonaventura, J Carter, F Chan, C Dalrymple, A Ferrier, G Gard, N Hacker, R Hogg, R Houghton, D Marsden, K McIlroy, G Otton, S Pather, A Proietto, G Robertson, G Wain, F Wong.

QLD- J Armes, A Crandon, M Cummings, J Nicklin, L Perrin, A Obermair, B Ward.

SA- M Davy, T Dodd, J Miller, S Paramasivum, J Pierides, F Whitehead.

TAS- P Blomfield, D Challis.

VIC- D Allen, S Hyde, P Grant, D Neesham, J Pyman, M Quinn, R Rome.

WA- B Brennan, I Hammond, Y Leung, A McCartney, C Stewart, J Thompson.

*Contributions of specific individuals may be denoted by use of superscripts.*


**B. ACKNOWLEDGEMENTS FOR STUDIES THAT INCLUDE ANECS AS ONE OF SEVERAL AUTHORS**

We would like to thank all the women who participated in the study.

We gratefully acknowledge the cooperation of the following institutions:  *South Wales:* John Hunter Hospital, Liverpool Hospital, Mater Misericordiae Hospital (Sydney), Mater Misericordiae Hospital (Newcastle), Newcastle Private Hospital, North Shore Private Hospital, Royal Hospital for Women, Royal North Shore Hospital, Royal Prince Alfred Hospital, St George Hospital, Westmead Hospital, Westmead Private Hospital; *Queensland:* Brisbane Private Hospital, Mater Misericordiae Hospital, Mater Private Hospital, Royal Brisbane and Women's Hospital, Wesley Hospital; *South Australia:* Burnside Hospital, Calgary Hospital, Flinders Medical Centre, Queen Elizabeth Hospital, Royal Adelaide Hospital; *Tasmania:* Royal Hobart Hospital; *Victoria:* Freemasons Hospital, Mercy Hospital for Women, Royal Women's Hospital; *Western Australia:* King Edward Memorial Hospital, St John of God Hospitals Subiaco & Murdoch.

PLUS DEPENDING ON JOURNAL POLICY

*EITHER:*

 *Clinical Collaborators:* NSW- S Baron-Hay, D Bell, A Brand, S Braye, A Bonaventura, J Carter, F Chan, C Dalrymple, A Ferrier, G Gard, N Hacker, R Hogg, R Houghton, D Marsden, K McIlroy, G Otton, S Pather, A Proietto, G Robertson, G Wain, F Wong; QLD- J Armes, A Crandon, M Cummings, J Nicklin, L Perrin, A Obermair, B Ward; SA- M Davy, T Dodd, J Miller, S Paramasivum, J Pierides, F Whitehead; TAS- P Blomfield, D Challis; VIC- D Allen, S Hyde, P Grant, D Neesham, J Pyman, M Quinn, R Rome; WA- B Brennan, I Hammond, Y Leung, A McCartney, C Stewart, J Thompson. *Project Staff:* S Moore, K Ferguson, B Alexander, L Green, J Hallo, L Jackman, J Maidens, A Marshall, A Mellon, E Minehan; K Nattress, B Ranieri, D Roffe; H Shirley, A Stenlake, S Webb, J White.

*OR:*

We also acknowledge the contribution of our clinical and scientific collaborators and their staff and all of the ANECS project staff. See <http://www.aneecs.org.au/> for full listing.

### **C. STATEMENT RE ETHICAL APPROVAL**

This study was approved by the Human Research Ethics Committees at the Queensland Institute of Medical Research, ...\*, and all participating hospitals.

*\*Add any other institutions involved.*

For studies including women through the cancer registries, this will include: New South Wales Cancer Council, The Cancer Council South Australia, The Cancer Foundation of Western Australia, Cancer Council Tasmania.

**D. STATEMENT RE FUNDING:** This study was supported by the Australian National Health and Medical Research Council (ID 339435), and the Cancer Council Tasmania (ID403031).

**APPLICATION FORM TO ANECS FOR WORK INVOLVING USE OF BIOLOGICAL MATERIAL AND/OR DATA**

**Title of Project:** \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_

**Institution:** \_\_\_\_\_

**Address :** \_\_\_\_\_

**Phone Number:** \_\_\_\_\_ **FAX:** \_\_\_\_\_

**e-mail:** \_\_\_\_\_

**Other Investigators (Institution):**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

We/I hereby seek permission from ANECS to undertake the research work detailed in the attached proposal according to the conditions specified by ANECS. We/I will sign the relevant Material Transfer Agreements and will not distribute the material or data to third parties. We/I will list as the Australian National Endometrial Cancer Study as an author on any resulting publications, in addition to any ANECS members who fulfil authorship criteria for the study as it progresses. We/I will meet the costs involved in preparing and shipping biological specimens and in extracting data from the central database. We/I realise that there is the potential that this human biological material may contain infectious agents, and therefore should be handled appropriately.

**Signed:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signed:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signed:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signed:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## **CHECKLIST OF MATERIAL REQUIRED AS PART OF FULL OR PILOT APPLICATIONS FOR BIOSPECIMENS AND/OR DATA**

**Items in BOLD need to be supplied for all projects, including internal applications.**

**Scientific proposal (up to six pages) including aims, hypotheses to be tested, significance, background, research plan with details of methods to be used and references. This should include the rationale for the number and amount of samples requested, including considerations of statistical analysis and statistical power. Less than one page is required for a pilot project.**

**List of biological material requested including the type of sample, the number of samples, and the amount of sample (if appropriate).**

**Completed ANECS Data Request Form (see attached)**

**Evidence of ethical clearance for the project including copies of approved institutional human research ethics applications and all correspondence with the human research ethics committee. Where applicable this must be provided from each of the participating institutions. If Ethics Approval has not been obtained at the time of submission, then final ANECS approval will be conditional on receipt of copies of Ethics approvals documents from the relevant institutions.**

Evidence of approval for a grant application that has already undergone peer review by a funding agency, including copies of the referees' reports. This is not required for pilot projects.

Names of three suitable referees for grants that have not already undergone peer review or for which peer review from an external granting body is not pending. Applicants may also nominate people whom they do not wish to review the application. This is not required for pilot projects.

Information on the resources available to conduct the research (including source of funds, personnel, and maintenance).

Publications of the Chief Investigator(s) for the last five years.

Suggested timeline for the project including batch sizes and reasonable monitoring procedures for ANECS to use, and predicted time for submitting new data generated by the project to the ANECS database. Indicate when the first request for data and/or biological specimens will be made following approval of the project. Successive batches may not be shipped until data from the previous batch(es) have been received at the central ANECS database according to the agreed schedule. In the event that the data are incomplete or are otherwise unacceptable, ANECS reserves the right to withhold further shipments of material.

For applications involving biospecimens, suggested protocol for shipping, including (a) mode of shipping, (b) address for shipping, and (c) suggested arrangement for payment of shipping.

**A outline of consulting agreements, collaborations and research projects between investigators named on the application and commercial organisations.**

# ANECs Data Request Form

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Name:

Organisation:

ANECs Project:

Date of request:

Date data required:

## Your contact details

E-mail:

Fax:

Phone:

## Names of other contact people for this project

Name

E-mail:

Phone:

Name

E-mail:

Phone:

**Please enter full details of your request here:**

**In which format would you like your data, e.g., MS Excel spreadsheet:**

**A data request number and contact name will be sent to you as soon as possible. Please email the contact person if you need to clarify details of your request.**

## **CONTACT INFORMATION**

Dr Amanda Spurdle [Amanda.Spurdle@qimr.edu.au]

Dr Penny Webb [Penny.Webb@qimr.edu.au]

### **ANECS Project Manager**

Suzanne Moore [Suzanne.Moore@qimr.edu.au]

### **Appendix 1: Future Directions as listed in the parent NHMRC grant application**

- Matching of cases with the Australian Death Index to obtain survival information, in order to identify clinical, histopathologic and molecular factors related to survival.
- Follow up of positive genetic associations using the haplotype approach, namely screening markers spanning the gene to identify genetic regions/combinations associated with risk.
- Follow up of positive associations with genetic polymorphisms detected by case-control analysis by assessing risk associated with the same polymorphism in relatives of cases. This will involve future collection of material from family members of cases.
- Expression profiling of tumour tissues, to molecularly define different histological subtypes by relative levels of gene expression, and identify candidates for further genetic studies.
- Tumour protein profiling to identify protein biomarkers of tumour aggression. In collaboration with Dr Darren Krause at QIMR, we have already initiated a pilot project with this aim, and the material collected as part of this study would provide resources for confirmation of our findings.
- Building on gene and protein expression profiling studies, to map the progression of endometrioid cancer subtype tumourigenesis from simple hyperplasia through to carcinoma

### **Appendix 2: Membership of the ANECS Working Committee**

The ANECS Committee will comprise contributors covering a range of expertise, and will include members from the investigator team and the wider collaborative group:

Amanda Spurdle (genetics)

Penny Webb (epidemiology)

Joanne Young (tumour biology)

Two clinicians from the ANECS collaborative group, nominated annually by the ANECS collaborative group.

An external scientist will be called in if necessary if additional independent expertise is required.