ACCESS POLICY

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ACCESS TO AOCS DATA AND SAMPLES
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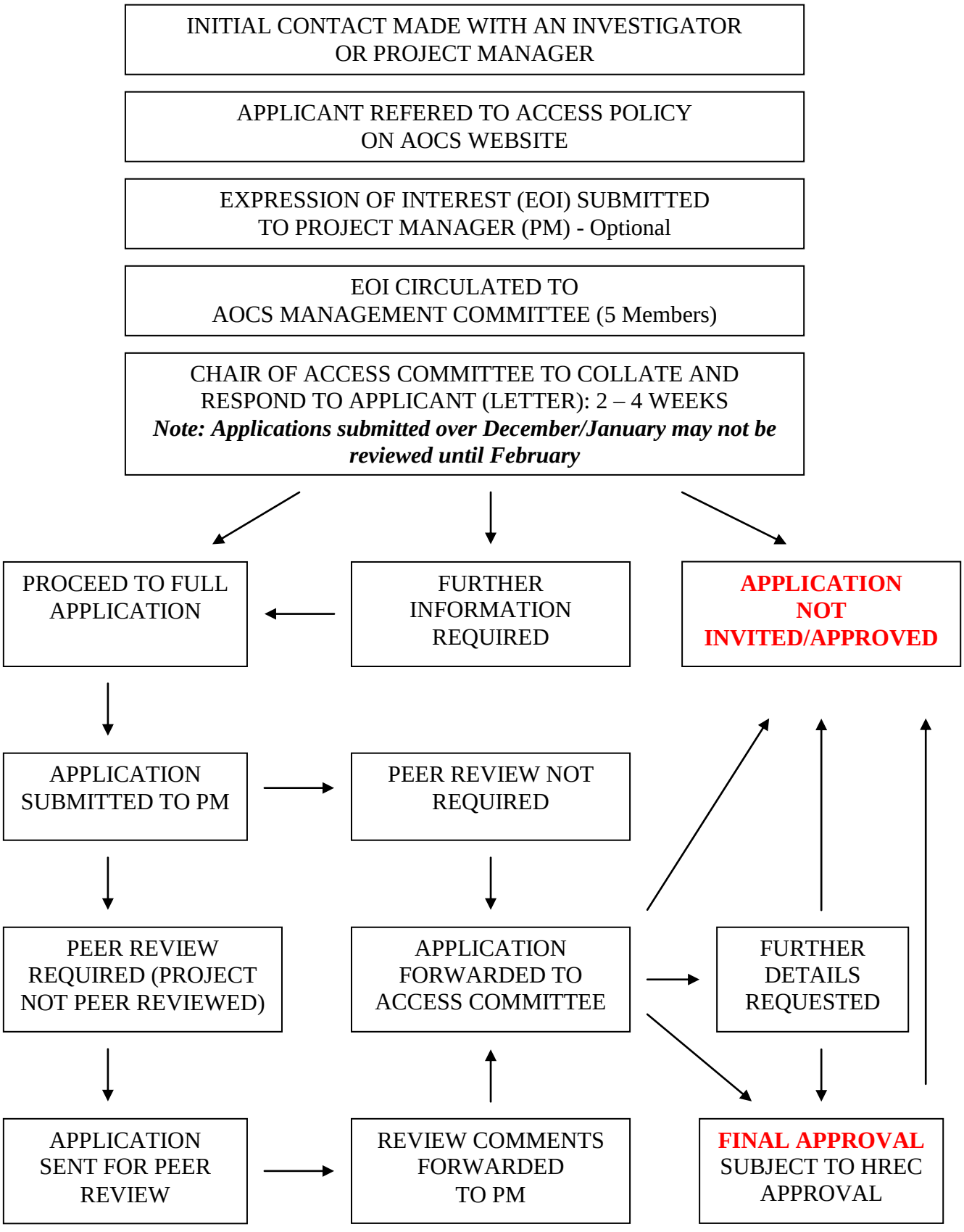

AUSTRALIAN OVARIAN CANCER STUDY

Policies and Procedures for Access to Data and/or Biological Specimens

Who can apply to use AOCS data and/or biospecimens?

The resource will be widely available to any investigator(s) working in cancer research, following formal application and review by the AOCS Access Committee (Appendix 1), however projects that have the potential to benefit Australian women will receive priority.

These policies will be reviewed annually by the AOCS Program Management Committee.

When can an application to AOCS be made?

After January 2006, applications can be submitted to the AOCS Access Committee at any time, and will be discussed at the monthly AOCS Program Management Committee teleconference. The applicant should detail any anticipated impact on the progress of the current DoD-funded projects.

How does an application to AOCS for a research project get approved?

The steps involved in applying to AOCS for access to biological material and/or data held by AOCS are similar to those used in other large-scale studies. In brief they involve:

- making initial contact with a member of the AOCS Program Management Committee to determine the suitability of the resource for the proposed project;
- sending an Expression of Interest (Appendix II) to Laura Galletta, the AOCS Project Coordinator, at the Peter MacCallum Cancer Centre for circulation to the AOCS Program Management Committee (optional);
- submitting a research proposal together with the usual ancillary material to the AOCS Access Committee (c/o Laura Galletta). This application will be requested once the Expression of Interest has been reviewed by the AOCS Access Committee and must be submitted within six months of the request date. It may be appropriate in some instances, at the discretion of the Chair of the Access Committee, for the EOI and full application to be submitted together, for example where the AOCS component of the study is part of a larger application for funding that has already been peer reviewed.

Full details concerning the application and review process are provided below. If the proposal has not been approved by, or submitted to a funding agency, the Access Committee may seek the opinion of external reviewers. Final approval for any project will be subject to appropriate ethical clearance.

What are the responsibilities of investigators who use AOCS material?

The Chief Investigator(s) of the project agree:

- to obtain clearance for the project from all appropriate institutional ethics committees including, at a minimum, those at their host institution. AOCS will submit an annual summary report of all projects approved by the Access Committee to the QIMR and PMCC Human Research Ethics Committees for notification;
- to sign Materials Transfer Agreements (MTA) issued by PMCC and, if required, sign a MTA Extension Form;
- to pay for the costs of preparing and shipping biological materials if requested by the AOCS Program Management Committee;
- to pay for the costs of extracting or preparing data from the AOCS databases if requested by the AOCS Program Management Committee;
- 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 AOCS Program Management Committee reserves the right to terminate the project and recover any outstanding data and biospecimens;
- not to distribute materials or data to investigators or institutions who are not named in the approved application;
- not to use AOCS data and/or materials for purposes other than those agreed to in the approved protocol, without obtaining the relevant signed Material Transfer Agreement (MTA);
- to submit draft papers to the AOCS Program Management Committee prior to submitting to a journal for publication;
- to include "The Australian Ovarian Cancer Study Group" as an author on all publications using AOCS resources;
- to acknowledge the funding bodies and collaborators that have contributed to AOCS on all publications using AOCS resources; (the appropriate wording can be found in the AOCS publication policy at www.AOCStudy.org)
- to acknowledge the AOCS on all publicity related to the project;
- to return the data and/or any unused materials to AOCS and to submit all new data generated by the project to the central AOCS databank at the conclusion of the study (i.e. after publication of the data, or within 12 months of completion of the project if the data are not the subject of a manuscript under review);

How does AOCS protect the finite 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 AOCS 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 less likely to be approved.

Requests will fall into three categories as follows-

Category I- Epidemiology data, Biospecimens (and/or associated data) and CFU data required

Category II- a) Epidemiology data and Biospecimens (and/or associated data) required
b) Epidemiology data and CFU data required
c) Biospecimens (and/or associated data) and CFU data required

Category III- a) Epidemiology data only required
b) Biospecimens (and/or associated data) only required
c) CFU data only required

Because of the finite nature of the resource, AOCS 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 AOCS can monitor progress – for example the publication of reporting of intermediate results. Because of the difficulties of shipping frozen material, more stable reagents - such as RNA, rather than frozen tissue - will be supplied whenever possible).

How does AOCS protect the human subjects?

All AOCS participants have consented to having their data and materials being used for approved cancer research. Every research project must however be first cleared by the ethics committees at the investigators' host institution(s), QIMR and PMCC.

How does the AOCS assess the quality of biological or molecular information being submitted to the database?

Primary responsibility for the ethical and scientifically valid use of AOCS biospecimens and data rests with the Chief Investigators of the individual research projects. However, should problems arise, AOCS reserves the right to initiate confirmatory analyses of materials previously released to researchers for the purposes of quality control. In extreme cases AOCS 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.

Procedures for applying to use biospecimens and / or data collected by AOCS (see Appendix III)

Before making an application, researchers should contact a member of the Program Management Committee (Appendix I) to discuss the rationale, feasibility and the appropriateness of the AOCS resource for the proposed study.

If deemed to be appropriate, the applicant will then be sent the Guidelines and Application Form, and can choose to either submit an Expression of Interest (Appendix II) to the Project Manager for circulation to the AOCS Program Management Committee or submit a full application as detailed below. Comments on the Expression of Interest will be given within one week of receipt. As mentioned, this step is optional, however recommended if applicants are not familiar with the resource.

The full application should be submitted according to the Application Form, attaching the relevant documents. The AOCS Access Committee may send applications that have not had prior peer review to external referees. If a proposal is awaiting approval from the relevant Ethics Committees, or currently under peer review by a granting agency, AOCS can provide a letter stating that the samples/data requested are available, subject to ethical approval and/or final approval by AOCS once funding is obtained.

Applications and referees reports will be reviewed by the AOCS Access Committee to assess whether the application comprises a scientifically justifiable, feasible, and high priority use of the available material and/or data. The Committee may suggest mechanisms and timescales for the delivery of the requested samples and/or data as well as the costs involved. They may also suggest changes to the proposed application and try to facilitate communication and collaboration between groups working on similar topics. The applicant may be asked to respond to reviewers' comments in writing.

The Program Manager and two Project Managers will be present at the meetings to provide comment on the practicalities of the request, but they will not contribute to the final decisions. Applications will be scored and ranked on the basis of standard criteria including the novelty, significance and feasibility of the project and the track record of the investigators. Special consideration will be given to projects where one or more of the Investigators is an AOCS contributor. This will be based on the level of contribution (eg. to study design, patient recruitment, sample or data collection, pathology review etc). Reasons will be given for refusal of all or part of the proposed use of material. Conditions on, or restrictions to, use of material or data may be made.

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.

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.

Annual progress reports will be required by AOCS, and AOCS 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.

Projects will be approved or a maximum of three years, after which a renewal application must be lodged. In the review of renewal applications, and additional, new applications from investigators with approved projects, the AOCS Program Management Committee will take into account the productivity on the previous projects.

What about pilot projects?

Investigators may request permission to conduct a pilot project with the intent of establishing the rationale, feasibility or power of full application. The results of a pilot study would not normally be expected to be publishable.

A pilot project involves limited numbers of specimens, in general:

< 20 germline DNA samples;

< 20 RNA or DNA samples from tumours ;

- slides or DNA from <15 pathology blocks.

However, the sample size will need to be sufficient to achieve the stated aims.

The same processes, application forms and decision criteria will be required for pilot and full applications, except that the need to full peer-review will be waived for pilot projects. 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 AOCS Access Committee.

In addition, AOCS will identify a subset of samples with large amounts fresh frozen tumour tissue collected (>3g). This resource will be made available to pilot projects.

Can additional investigators be added to approved AOCS projects?

Yes, the procedure in this case is that the PI of the project will request a signed MTA from any new collaborator to whom they wish to pass on material. This will then be forwarded to Laura Galletta who will pass it on to the AOCS Program Management Committee for approval.

Can amendments to the project be applied for throughout the course of the study?

Yes, amendments to the project can be applied for throughout the course of the study. Amendments need to be submitted using the AOCS Amendment / Notification form (Appendix III) and can be used when requesting additional samples and/or data for previously approved projects.

Once the Amendment form is completed and sent to the Project Coordinator, it will then be circulated to the AOCS Access Committee and to the Head of each relevant Core for approval. If the amendment is deemed substantial, then a new application may be requested.

The same form can be used notify the Access Committee of a new proposed use of an AOCS resource you have already accessed. A Notification can be used when no ethical implications exist and there is no impact on the AOCS resource. Once a completed form is received by the Program Manager, it will be circulated to the Access Committee and to the Head of each relevant Core for notification.

What if there is a conflict of interest with a member of the Access Committee?

Members of the AOCS Access Committee with a Conflict of Interest will not participate in the Access Committee decision.

Can investigators appeal the decision made by the AOCS Access Committee?

Investigators can appeal the decision if they are not happy with the outcome. In such instances, the AOCS Scientific Advisory Committee will be asked to review the application.

Appendix I

Management of the Australian Ovarian Cancer Study

The Principal Investigator of the AOCS Program is Prof David Bowtell, Director of Research at the Peter MacCallum Cancer Centre. Prof Bowtell is also Principal Investigator on the Biospecimens Core and has final responsibility for decisions concerning this material. Professor Adèle Green is Principal Investigator on the Epidemiology Core and has final responsibility for decisions concerning these data. Dr Anna deFazio is head of the Clinical Follow-up Core and has final responsibility for decisions concerning these data. Prof Bowtell, Prof Green and Dr deFazio will be assisted in these tasks by:

The **AOCS Program Management Committee** comprising the Principal Investigators of the various components of the Program: David Bowtell, Adèle Green, Georgia Chenevix-Trench (PI: Project 3), Penny Webb (PI: Project 2), Anna deFazio and Dorota Gertig. The two core Project Managers (Suzanne Moore and Jillian Hung) and the AOCS Project Coordinator and Project Manager (Laura Galletta and Nadia Traficante) are 'non-voting' members of the Committee.

The **AOCS Access Committee** comprising members of the AOCS Program Management Committee, namely David Bowtell, Adèle Green, Georgia Chenevix-Trench, Penny Webb and Anna deFazio and 2 additional independent consultant (scientist and/or clinician): Gillian Mitchell and Ian Campbell.

The **AOCS Scientific Advisory Committee** of consultants (scientists, including an overseas member; clinicians; a pathologist; and consumer representative) will advise on scientific issues and concerns regarding access to data and specimens.

The **AOCS Study Group** comprises all investigators who have directly contributed to the AOCS resource in terms of study design, recruitment of patients, collection of biological specimens, pathology review etc.

Appendix II

AOCS EXPRESSION OF INTEREST FORM

AOCS EXPRESSION OF INTEREST

PRINCIPAL INVESTIGATOR		
Name:	Affiliation:	
Address:		
Suburb	State	Postcode
Phone:	Email:	

CO INVESTIGATOR (S)	
Name:	Affiliation:
Name:	Affiliation:

AOCS CONTACT PERSON

TITLE OF PROJECT

BRIEF SUMMARY OF STUDY (300 words)

METHODS- ***design, statistical power of study***

DOES THE PROJECT HAVE ETHICS APPROVAL? ☐ **YES** ☐ **NO**

IF NOT, IS AN HREC APPLICATION IN PROGRESS? ☐ **YES** ☐ **NO**

HAS THE PROJECT BEEN PEER REVIEWED? ☐ **YES** ☐ **NO**

IF YES, PLEASE SPECIFY _____

DO YOU HAVE FUNDING FOR THIS STUDY? ☐ **YES** ☐ **NO**

IF NOT, IS FUNDING BEING SOUGHT? ☐ **YES** ☐ **NO**

Appendix III

AOCS AMENDMENT/NOTIFICATION FORM

This form is to be used when requesting additional samples and/or data for currently approved AOCS projects or to notify the Access Committee of the proposed use of the AOCS resource that you have already accessed.

*PROJECT #:*_____ *DATE:*_____

Please tick one of the following checkboxes -

☑ NOTIFICATION OF PROPOSED USE OF RESOURCE - **YES** **NO**

☐ AMENDMENT TO REQUEST ADDITIONAL DATA/SAMPLES - **YES** **NO**

PRINCIPAL INVESTIGATOR	
Name:	Affiliation:

CO INVESTIGATOR (S)	
Name:	Affiliation:
Name:	Affiliation:

AOCS CONTACT PERSON

TITLE OF PROJECT

BRIEF SUMMARY OF PROGRESS

DESCRIPTION OF AMENDMENT (*Not Required For Notification*)

JUSTIFICATION

DOES THE PROJECT HAVE ETHICS APPROVAL? **YES** **NO**

IF NOT, IS AN HREC APPLICATION IN PROGRESS? **YES** **NO**

HAS THE PROJECT BEEN PEER REVIEWED? **YES** ☐ **NO**

IF YES, PLEASE SPECIFY _____

_____

_____

DO YOU HAVE FUNDING FOR THIS STUDY? **YES** ☐ **NO**

IF NOT, IS FUNDING BEING SOUGHT? **YES** **NO**

OFFICE USE ONLY

☐ **AMENDMENT FORWARDED TO ACCESS COMMITTEE FOR APPROVAL**

☐ **AMENDMENT SUBSTANTIAL- NEW APPLICATION REQUIRED**

Appendix IV

AOCS APPLICATION FORMS

Procedures for Access to AOCS Biospecimens and/or Data for Full and Pilot Projects

1. Before making an application for bio-specimens and/or data, researchers should discuss the rationale, feasibility and the appropriateness of the AOCS resource for the proposed study with a member of the AOCS Program Management Committee

2. The applicant can download the Guidelines and Application Form from the AOCS web site *(www.aocstudy.org)*. Applicants can choose to submit an Expression of Interest to Laura Galletta at the Peter MacCallum Cancer Centre for circulation to the AOCS Program Management Committee to allow the members to comment on the application, or proceed to a full application that will be circulated to the full AOCS Access Committee.

3. Applications must be made on and according to the Application Form, attaching relevant documents according to the appropriate checklist. Completed applications should be sent by email to Laura Galletta (**laura.galletta@petermac.org**) at the Peter MacCallum Cancer Centre for forwarding to the AOCS Access Committee.

4. Full applications that have not had prior peer review may be sent to referees. If a proposal is currently under peer review by a granting agency, AOCS can provide a letter stating that the samples requested are available, subject to final approval by AOCS once funding is obtained.

5. Applications and referees reports will be reviewed by the AOCS Access Committee, which will assess whether the application comprises a scientifically justifiable, feasible, and high priority use of the biological material and/or data currently available. The applicant may be asked to respond to the reviewers' comments in writing. The committee may suggest some changes to the proposed application and will try to facilitate communication and collaboration between groups working on similar topics.

6. Reasons will be given for refusal of all or part of the proposed use of material and/or data, and this may occur even if the grant proposal has approved funding. Conditions on, or restrictions of, use may be made.

7. On receipt of signed and written agreement by the applicant, and evidence of ethical approval, the project can proceed according to the agreed protocol.

8. Any significant deviations from the agreed protocol must be sent by the applicants in writing for approval before proceeding.

9. Samples will be shipped and data will be transferred from the AOCS database according to the agreed protocol.

10. Annual progress reports will be required by AOCS by June 1 for all projects that have been approved more than 12 months previously. Laura Galletta will notify all investigators when progress reports are due.

11. Data and biological material will be supplied as soon as possible after a request is approved. The onus is on the investigator to re-submit the application at a later date as the AOCS resource grows if additional material and/or data is required for

the same project. Alternatively, if the original application was for ‘all’ of the specified material and/or data, then the onus is on the researcher to re-contact Laura Galletta regularly for additional material and/or data as it becomes available.

12. AOCS may charge the researcher for the preparation and shipping of biological materials and for extracting and preparing data.

13. AOCS reserves the right to withhold the supply of further material and/or data if the rate of progress is unacceptable.

CHECKLIST OF MATERIAL REQUIRED AS PART OF EOI FOR ACCESS TO BIOSPECIMENS AND/OR EPIDEMIOLOGY, CLINICAL OR MOLECULAR DATA

- **Brief summary of study**

- **List of biological material requested including the type of sample, the number of samples, and the amount of sample**

- **Summary of epidemiological and/or clinical datasets requested (outline of levels of datasets available below)**

- **Outline of methods**

- **Objectives and likely benefits**

AOCS Clinical Follow-Up Datasets

Extensive clinical information is collected on patients enrolled in AOCS. As the data are derived from medical records there may be some data that are not readily available for specific cases. Not all clinical follow-up information is required for all research projects and some datasets are more straightforward to extract and interpret than others. The following are examples of data-sets that can either be supplied or will be able to be supplied in the future for project request:

- *Level 1 (Basic Dataset)*
  - Patient age;
  - FIGO stage/sub-stage;
  - Residual disease (nil, <1 cm, >1 cm);
  - Type of primary treatment (Surgery/drug type/neo-adjuvant);
  - Relapsed or not; Time to relapse (or last follow-up);
  - Dead or alive; Time to death (or last follow-up).

- *Level 2 (Intermediate Dataset)*
  - Data on previous / concurrent malignancies and previous treatment;
  - Details of primary chemotherapy (cycles, dose, route etc);
  - Details of residual disease (extensive miliary disease);
  - CA125 levels / assays;
  - Clinical Trial;
  - Basis for determining response;
  - Cause of death.

- *Level 3 (Advanced Dataset - not yet available)*
  - Data on genetic testing;
  - Details on subsequent treatment (following relapse);
  - Best response to primary and subsequent treatment.

AOCS Epidemiological Datasets

Extensive Epidemiological information is collected on each patient enrolled in AOCS. The following are examples of datasets that can be supplied for project requests:

- *Level 1 (Variables that have already been cleaned and derived) e.g.*
  - Ethnicity (Caucasian/Black/Asian/ATSI/Other/Mixed based on majority of grandparents);
  - Previous breast cancer, history of breast or ovarian cancer in 1st degree relative;
  - Height, weight and BMI;
  - Cigarette smoking / pack years / average alcohol consumption;
  - Parity, age at first and last birth;
  - Duration of use of hormonal contraceptives, any use of HRT;
  - Previous hysterectomy or tubal ligation

- *Level 2 (Variables that need some cleaning and/or simple derivation)*
  - More detail re family history of cancer;
  - Use of medications;
  - Age at menopause.

- *Level 3 (Variables that need extensive cleaning and/or complex derivation)*
  - Use of OC's and/or HRT by type of hormones.

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

PRINCIPAL INVESTIGATOR		
Name:	Affiliation:	
Address:		
Suburb	State	Postcode
Phone:	Email:	

CO INVESTIGATOR (S)	
Name:	Affiliation:
Name:	Affiliation:

AOCS CONTACT PERSON

TITLE OF PROJECT

BRIEF SUMMARY OF STUDY (300 words)

SECTION 1

In order for the committee to determine whether your request is an appropriate use of this valuable resource, please provide:

a) Background and justification of the proposed research

b) Hypotheses and aims

c) Feasibility of the work, including design, statistical power, access to key technologies, experience of the host laboratory, and available staff and funding to support the work

d) Indicate why the work would benefit from the use of AOCS samples, rather than other banked ovarian samples

e) Justify the number and type of samples requested in the context of the proposed research.

f) Indicate whether obtaining samples in batches is feasible and whether there is merit in sending part of the requested material to gain feedback on progress before the complete number of samples is sent

Please make responses as succinct as possible and provide this information in 6 pages or less.

Pilot studies, involving approximately 20-30 samples or less, or for example which provide preliminary information for a grant application, should be described in ~2 pages

SECTION 2

In order to assess the impact of your request on the resource, and the workload required to access the material/data, please indicate the number, amount, and type of sample (eg germline DNA, tumour DNA, frozen tumour RNA, blocks, slides), and what data is required (clinical, epidemiological, genomic or other) –

Type of sample _____

_____

Number of samples _____

Amount of sample (if applicable) _____

List the epidemiological and/or clinical and/or genomic data requested-

SECTION 3

It is important that your work accords with the ethical standards that govern use of the AOCS resource. Please provide 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.

DOES THE PROJECT HAVE ETHICS APPROVAL? YES ☐ NO ☐
(if yes, please provide evidence)

IF NOT, IS AN HREC APPLICATION IN PROGRESS? YES ☐ NO ☐

SECTION 4

To assist the committee in assessing the merit of the science proposed it is useful know if the work has been peer-reviewed and has successfully obtained grant funding. If so, please provide evidence of peer-reviewed success of the proposed research and wherever possible, AOCS would appreciate receiving copies of the referees' reports.

HAS THE PROJECT BEEN PEER REVIEWED? YES ☐ NO ☐

IF YES, BY A GRANTING BODY? YES ☐ NO ☐
(if yes, please provide evidence)

SPECIFY GRANTING BODY _____

BY OTHER PARTY? Please Specify _____

DO YOU HAVE FUNDING FOR THIS STUDY? YES ☐ NO ☐
(if yes, please provide evidence)

IF NOT, FUNDING BEING SOUGHT? YES ☐ NO ☐

SECTION 5

Where the proposed research has not been subject to peer-review, as commonly occurs with pilot experiments or where the work involves an extension of very recent research findings, the committee sends the application to several external scientists for independent feedback to the committee. Please indicate names of three suitable referees and whether there are any individuals who should not receive the report. Pilot studies are not normally subject to peer-review outside the committee.

1. Name:
2. Name:
3. Name:

Applicants may also nominate people whom they do not wish to review the application. This is not required for pilot projects.

1. Name:
2. Name:

SECTION 6

Please list publications of the Chief Investigator(s) for the last five years.

SECTION 7

If samples are being requested, please complete the following-

Mode of shipping

Address for shipping

CONTACT NUMBER

Suggested arrangement for payment of shipping

If data are being requested, please indicate preferred and acceptable formats-

☐ **Excel** ☐ **Access** ☐ **SAS** ☐ **Other (specify):**

SECTION 8

Collaborations with commercial organizations that involve the use of AOCS material, data or information arising from the work should be listed so as the committee can assess any aspects of the proposed work that may impact on AOCS.

CONTACT INFORMATION

Contact information for Ms Laura Galletta at the Peter MacCallum Cancer Institute

Laura Galletta - laura.galletta@petermac.org
Telephone – (03) 9656 1789

Members of the AOCS Access Committee

Prof David Bowtell	david.bowtell@petermac.org
Dr Anna DeFazio	anna_defazio@wmi.usyd.edu.au
Dr Penny Webb	penny.webb@qimr.edu.au
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Dr Gillian Mitchell	gillian.mitchell@petermac.org
A/Prof Ian Campbell	ian.campbell@petermac.org

Members of the AOCS Scientific Advisory Board

Dr Paul Meltzer

Dr Sue Hankinson

Dr Anne Hamilton

Ms Paula Gurry