Omico.

INFORMATION AND POLICIES

ACCESS TO OMICO DATA AND BIOSPECIMENS

1. What is Omico?

Omico is an Australian, national, not-for-profit organisation uniting medical research institutes, researchers, clinicians, industry partners and government to improve outcomes for Australian cancer patients using precision oncology.

2. What is Omico's mission?

To apply the principles of precision oncology to

- bridge the gap – bring the next generation of healthcare to cancer patients
- use innovation to inform the new 'standard of care' for cancer patients
- stimulation innovative research into the prevention, earlier diagnosis and better treatment of cancers with unmet need
- increase access of Australian patients with cancer to innovative therapy
- build partnerships between governments, community, academic institutions and industry

3. What is the procedure for applying to Omico for access to data/biospecimens for research (Figure 1)?

I. Before making an application for biospecimens (with accompanying data), researchers may wish to confer with the Omico team on researchrequests@omico.org.au to investigate the rationale, feasibility and the appropriateness of the Omico resource for the proposed study.

   Application forms are available on the Omico website (www.omico.org.au) or from researchrequests@omico.org.au.

II. Applications must be made on and according to the Omico Application Forms (Project Application Form, Biospecimen Request Form, Data request Form) attaching relevant documents as indicated. Completed applications must be sent to researchrequests@omico.org.au.

III. In some cases applications that have not had prior peer review may be sent by Omico to referees. If a proposal is currently under peer review by a granting agency, Omico can provide a letter stating that the biospecimens requested are available, subject to approval by the Omico Access Committee once a full application has been submitted.

IV. Applications and referee reports will be reviewed by the Omico Access Committee, which will assess whether the application comprises a scientifically justifiable, feasible, and high priority use of the biospecimens currently available. The applicant may be asked to respond to the reviewers' comments in writing. The Omico Access Committee may suggest some changes to the proposed application and will try to facilitate communication and collaboration between groups working on similar topics. The Omico Access Committee will do their best to find fair resolutions to conflicts between competing groups who simultaneously submit overlapping applications. Applications for data will be ranked in order of priority.

V. Any member of the Omico Access Committee with a conflict of interest will be excluded from the review. The final decision will rest with Professor David Thomas as Chief Science

and Strategy Officer at Omico. Professor Thomas will then respond to the applicant in writing. Reasons will be given for refusal of all or part of the proposed use of biospecimens, and this may occur even if the grant proposal has approved funding. Conditions on, or restrictions of, use may be made.

VI. Projects that require direct interaction with Omico participants will always be referred to the relevant human research ethics committee for comment.

VII. Once the Material Transfer Agreement has been signed by both parties, and ethical approval obtained, the project can proceed according to the agreed protocol.

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

IX. Biospecimens will be shipped and data will be transferred according to the agreed protocol.

X. Annual progress reports will be required by Omico. Omico will notify all investigators when progress reports are due.

XI. Data and biospecimens 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 Omico resource grows if additional data or biospecimens are required for the same project. Alternatively, if the original application was for 'all' of the specified data or biospecimens, then the onus is on the researcher to re-contact Omico regularly for additional data or biospecimens as they become available.

XII. Omico may charge the researcher for the preparation and shipping of biospecimens and data exports.

XIII. Omico reserves the right to withhold the supply of further biospecimens if the rate of progress is unacceptable.

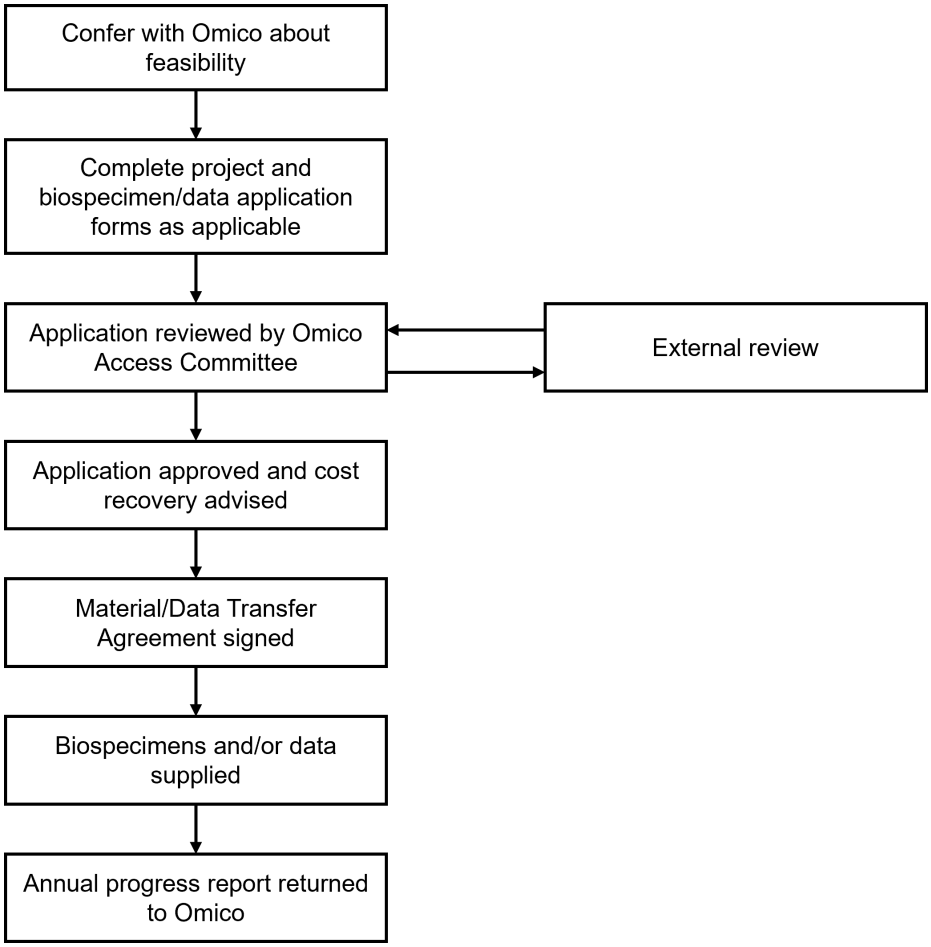

Figure 1. Procedure for applying to access Omico data and/or biospecimens

4. What biospecimens will Omico have available?

Omico participants donate peripheral blood which is processed and stored. FFPE tumour material may also be available. Further details can be found on the Biospecimen Request Form.

5. What information does Omico hold?

Family history, clinical, epidemiological, pathology and variant information are stored in a re-identifiable form on the central Omico databases. Omico data are available, in a de-identified manner, to researchers for approved research projects.

6. When can an application for access to Omico be made?

Applications can be sent to researchrequests@omico.org.au at any time.

7. How does an application to Omico for a research project get approved?

If the proposal has not been approved by or submitted to a granting agency, Omico may seek the opinion of external reviewers, whose reports will be reviewed by the Omico Access Committee. In the event of disagreement between the external reviewers and the various committee members, the final decision will rest with Professor David Thomas. In any event, final approval will be

subject to appropriate ethical clearance.

8. How are amendments to approved projects handled?

I. Amendments to the proposal originally approved by Omico may be submitted at any time during the lifetime of the approved project. Review by the Omico Access Committee will be at the discretion of the chair, Professor David Thomas, and determination as to whether an amendment requires full review will be the responsibility of the chair.

II. Amendments for minor changes in experimental procedures or small increases in the number of already approved biospecimens and/or the amount of data supplied by Omico will generally be approved automatically.

III. When the amounts of data and/or the types of biospecimens requested in the amendment are significantly greater in quantity or different in kind from those originally approved, the amendment will be sent for review to the Omico Access Committee and may be treated as a new proposal. Additional cost recovery charges will apply if it is considered a new proposal.

IV. Generally, requests to add on a separate, previously established, external project to an approved Omico project will be treated as a new proposal.

V. When investigators/collaborators who were not included in the original proposal are named in the amendment, the project leader should provide the following information

- the role of the new person in the project
- their location
- what Omico biospecimens and data (including overall numbers), will be provided to them
- the institutions to which the new investigators/collaborators are attached may be requested to sign an Omico Material Transfer Agreement.

9. Who should sign the Omico Material Transfer Agreement?

Omico requires that a Material Transfer Agreement be signed by any investigator who will receive a substantial amount of Omico data or biospecimens.

10. Can additional investigators be added to approved Omico projects?

Yes, the procedure in this case is that the PI of the project will request a signed Material Transfer Agreement from any new collaborator to whom they wish to pass on biospecimens. This will then be forwarded to researchrequests@omico.org.au who will circulate it to the Omico Access Committee for approval.

11. What are the responsibilities of investigators who use Omico biospecimens?

The Principal Investigator(s) of the project agree:

- To sign the Omico Material Transfer Agreement and not to distribute the biospecimen or data to investigators or institutions who are not named in the approved application.
- To list Omico as an author on any resulting publications, in addition to any Omico members who fulfil authorship criteria for the study as it progresses.
- To acknowledge the agencies that support Omico core activity in any resulting publications.
- To submit an annual report on this project to the Omico.
- To propose a timeline for monitoring the project.
- To meet the costs involved in preparing and shipping biospecimens and in extracting data from the central database, if requested by Omico.

- To notify Omico of study completion. All studies will be deemed complete after three years unless re-application is lodged.
- To lodge copies of relevant manuscripts utilizing the Omico resource with the Omico Access Committee.
- To submit published data back to Omico. In addition, Omico may request that unpublished data be sent to Omico if no publication has been submitted in the 12 months following completion of the project.
- To return unused biospecimens to Omico.
- To obtain a signed Material Transfer Agreement from any collaborator to whom they wish to pass on biospecimens for use in the approved project. This should be sent to researchrequests@omico.org.au with a request that Omico consider the addition of the collaborator to the project.

12. How does Omico protect the finite biospecimens resource?

Because biospecimens are a valuable and non-renewable resource (with the exception of lymphoblastoid cell lines) every effort should be made to extract the maximum amount of information from each biospecimen, and to avoid duplication of effort. For this reason Omico will encourage and facilitate cooperation and collaboration between potential competitors wherever possible. In the event that such cooperation cannot be achieved, the Omico Access Committee will make a final decision. Resolution may involve identification of non-overlapping biospecimen sets, or, if the projects are mutually exclusive, the rejection of a lower ranked application. Because of the finite nature of this resource, Omico is unlikely to ship large batches of biospecimens at one time, but instead will ask each applicant to suggest how the biospecimens may best be processed, including suggestions of batch sizes and milestones by which Omico can monitor progress - for example, the publication or reporting of intermediate results.

13. Returning information to Omico

Investigators using Omico biospecimens agree to submit new information found by that project to the central database so that molecular and biological information can be built up on these families and biospecimens.

14. How does Omico assess the quality of biological or molecular information being returned to Omico from approved projects?

Primary responsibility for the ethical and scientifically valid use of Omico biospecimens and data rests with the Principal Investigators of the research projects. However, should problems arise, Omico reserves the right, for the purposes of quality control, to initiate confirmatory analyses of biospecimens previously released to researchers. In extreme cases Omico may ask to review some raw data, and may institute some review before additional batches of biospecimens are given out. Discrepancies will be discussed with the investigator.