The ORIGINS Project Collaboration Policy

Version history

2015-12-23	Version 1
2016-12-06	Version 2
2017-06-08	Version 3
2018-02-01	Version 4
2018-07-23	Version 5
2018-10-01	Version 6
2020-08-31	Version 7
2021-01-13	Version 8
2024-06-13	Version 9

OVERVIEW AND CONTEXT

The early environment in pregnancy and early childhood determine physiological, structural, immune, metabolic, and behavioral development, and influence susceptibility to both early and later onset diseases.[1] Strategies to improve early life conditions and exposures in early life are critical in reducing the rising global burden of chronic disease.[2]

The ORIGINS Project (ORIGINS) is a collaborative initiative between the Telethon Kids Institute (Telethon Kids) and Joondalup Health Campus (JHC), establishing a new Western Australian (WA) birth cohort. ORIGINS is building a research platform through the establishment and development of a comprehensive research Database and Biobank. This will enable world class investigations into when and why non-communicable diseases (NCDs) develop, through the study of early environments, maternal and paternal physical health, and genetics. Our goal with ORIGINS is to reduce the rising epidemic of NCDs through 'a healthy start to life'.

The ORIGINS Project is fully integrated into the clinical and diagnostic services, led by a strong cohesive group of JHC Executive and Department Heads, across both public and private sectors. Clinicians (including midwives and laboratory staff) have research appointments in addition to clinical duties, promoting a research culture.

ORIGINS is a significant asset for the WA community as it will increase child and adolescent health research capacity, research productivity and translational impact. ORIGINS will have substantial short-term and long-term benefits for WA, providing a strong collaborative and training environment, international competitiveness, and will attract new expertise and strategic partnerships to WA.

Collaboration with ORIGINS provides numerous advantages and benefits for researchers. Through the ORIGINS research platform, researchers have the opportunity to access multiple longitudinal data sets, linked data, biological information, as well as the ability to embed novel interventions and clinical trials in an established cohort with existing infrastructure and resources. The ORIGINS research platform has international significance. Collaboration with ORIGINS provides access to a community of multidisciplinary researchers, health professionals, clinicians, and consumers locally, nationally, and internationally.

[1] Gluckman PD, Hanson MA, Cooper C, Thornburg KL. Effect of in utero and early-life conditions on adult health and disease. *N Engl J Med*. 2008;359(1):61-73.

[2] Hanson MA, Gluckman PD. Developmental origins of health and Disease – Global public health implications. *Best Pract Res Clin Obstet Gynaecol*. 2015;29(1):24-31.

SCOPE OF THIS POLICY

Collaboration and engagement are fundamental elements of ORIGINS at every level. As such, ORIGINS seeks to engage researchers, clinicians, service providers, government, and the wider community. As well as facilitating strategic long-term research capacity, ORIGINS is a pipeline for short-term productivity through a series of clinical trials, mechanistic studies, and targeted research questions – all with the ultimate goal of reducing the rising burden of NCDs. Collaboration and engagement with ORIGINS that is aligned with this goal is encouraged.

This document outlines the policy for collaboration and engagement with ORIGINS, including the conditions, behaviours, expectations and processes for all activities undertaken and requests for access to the Cohort, Project Resources, and/or Data.

Access may be for:

- Use of Cohort, to implement a new clinical trial, intervention, or observational study.
- Use of Cohort, to collect new Data (Biological Information, and/or Participant Information).
- Use of existing Data (Biological Information, and/or Participant Information).
- Data linkage.

DEFINITIONS

Any capitalised terms contained in this document have the same meaning as defined here unless the context requires otherwise.

1. "Biobank Governance Committee" comprises representatives relatively independent of The ORIGINS Project activities. Responsibilities include monitoring and reporting to the Executive on activities, operations, compliance and documentation pertaining to the ORIGINS Biobank and Biological Information.
2. "Biobank" a collection of biological samples collected for The ORIGINS Project.
3. "Biological Information" refers to all biological samples collected from ORIGINS Participants available for use by approved Researchers and the results of the analysis of those samples.
4. "Cohort" refers to the ORIGINS birth cohort, consisting of recruited mothers, children and fathers/partners who have provided consent to participate in The ORIGINS Project.
5. "Collaboration Agreement" means the agreement entered into between Telethon Kids and JHC in respect of The ORIGINS Project.
6. "Commercial Purposes" means the sale, lease, license, or other transfer of the data to a for-profit organisation. Commercial Purposes shall also include uses of the data by any organisation, including the recipient, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the data to a for-profit organisation. However, industrially sponsored academic research shall not be considered a use of the data for Commercial Purposes per se, unless any of the above conditions of this definition are met.
7. "Data" refers to all information stored in the ORIGINS Database and available for access by approved Researchers.
8. "Databank Governance Committee" comprises representatives relatively independent of The ORIGINS Project activities. Responsibilities include monitoring and reporting to the Executive on activities, operations, compliance and documentation pertaining to the ORIGINS Database.
9. "Database" a master cohort database incorporating Biological Information and Participant Information from ORIGINS Participants and any derived results, feedback, details of follow-up, biological and genetic data.
10. "Directorate" refers to the ORIGINS Directorate, comprising the Scientific Directors.
11. "Executive" refers to The ORIGINS Project Executive Group, comprising an equal number of representatives nominated from both parties: Telethon Kids Institute and Joondalup Health Campus. The Executive is responsible for overseeing the activities, objectives, implementation, and obligation of The ORIGINS Project and for administering this Policy.
12. "Further Project Contribution" means a further contribution of Project Resources agreed to be made by the Researcher(s), in addition to the Initial Project Contribution.

13. “Initial Project Contribution” means the initial contribution of Project Resources agreed to be made by the Researcher(s).
14. “Intellectual Property” means all intellectual property rights of any nature, including registered and unregistered copyright, inventions, patents, confidential information, registered and unregistered designs, trademarks and applications for any of the foregoing, but excludes Moral Rights.
15. “Participant Information” refers to all information collected on ORIGINS Participants and available for use by approved Researchers, including the results of the analysis of such information.
16. “Participants” comprise mothers, fathers/partners and babies attending the JHC premises during pregnancy and/or following birth who have given their consent to participate in The ORIGINS Project by providing Biological Information and Participant Information.
17. “Party” means any of Telethon Kids, JHC or the Researcher(s) (together, the “Parties”).
18. “Policy” refers to this Collaboration Policy.
19. “Project Contribution” means the Project Resources to be contributed by the Researcher(s) and includes both the Initial Project Contribution and any Further Project Contribution as the context requires.
20. “Project Management Group” refers to the ORIGINS Program Manager, Engagement and Quality Manager, Data Manager, Biobank Manager, Research and Translation Team Lead, Stakeholder Management Team Lead, and Sub-project Coordinator. It also includes representatives from Joondalup Health Campus and the Directorate.
21. “Project Resources” means resources (such as financial, staff, premises, consumables, or facilities) required for the purposes of enabling The ORIGINS Project to be implemented.
22. “Research Interest Groups” are formed according to the needs and interests of The ORIGINS Project as it evolves. Membership is based on expertise, interest, and commitment.
23. “Research Proposal” refers to the formal proposal submitted by Researcher(s) for consideration of access and/or use of the Cohort and/or Database.
24. “Researcher(s)” refers to the user, or group of users, seeking to collaborate and engage with The ORIGINS Project.
25. “Scientific Committee” comprises representatives from multiple research domains, the major tertiary institutions in WA, The ORIGINS Project Directorate, and at least one clinical representative of Joondalup Health Campus.
26. “Sub-project” refers to a nested research project/study that is incorporated into and/or connected to The ORIGINS Project via access to and/or use of the ORIGINS Cohort or Database.

This Policy will be effective from 18 January 2021 and will be applied to all current and future applications and Sub-projects.

This Policy will be updated as required and the latest versions of the relevant documents will be available on The ORIGINS Project website https://originsproject.telethonkids.org.au/. It is the responsibility of the Researchers to be aware of and adhere to any changes.

All enquiries should be directed to The ORIGINS Project Research and Translation Team ORIGINSResearch@telethonkids.org.au.

CONTENTS

LIST OF FIGURES

1. The ORIGINS PROJECT

1.1 Vision and Strategy

Vision

Happy people building healthy communities across the planet that empower us to realise our potential.

Strategic Imperatives

- Build a dynamic research platform to enable global health transformation (capacity)
- Provide responsive feedback to families and the community to facilitate change now (action)
- Collaborate globally and locally to extend our impact and reach (connectivity)
- Apply new technologies to accelerate and amplify change (creativity and ingenuity)
- Nurture and share a legacy that inspires global change, growth, sustainability and scalability (love, joy and awe)

1.2 Aims

1. Improve the health of the next generation through optimising the early environment (on all levels), early identification and timely intervention.

2. Develop an extensive Biobank and Database (research platform).

3. Make change: harmonised nested interventions clinical trials community-based programs.

4. Incorporate real time feedback: to Participants and health systems.

5. Utilise new technology platforms for personalised medicine: examine complex biological interactions (P4 'omics) in relation to bio-psycho-social determinants.

6. Integrate medical education, research and clinical care at the hospital.

7. Collaborate closely with other national and international cohort studies.

1.3 Governance Structure

The ORIGINS Project governance structure **(Figure 1.1)** has been established to outline the relationships between all organisational levels and ensure accountability from all relevant parties.

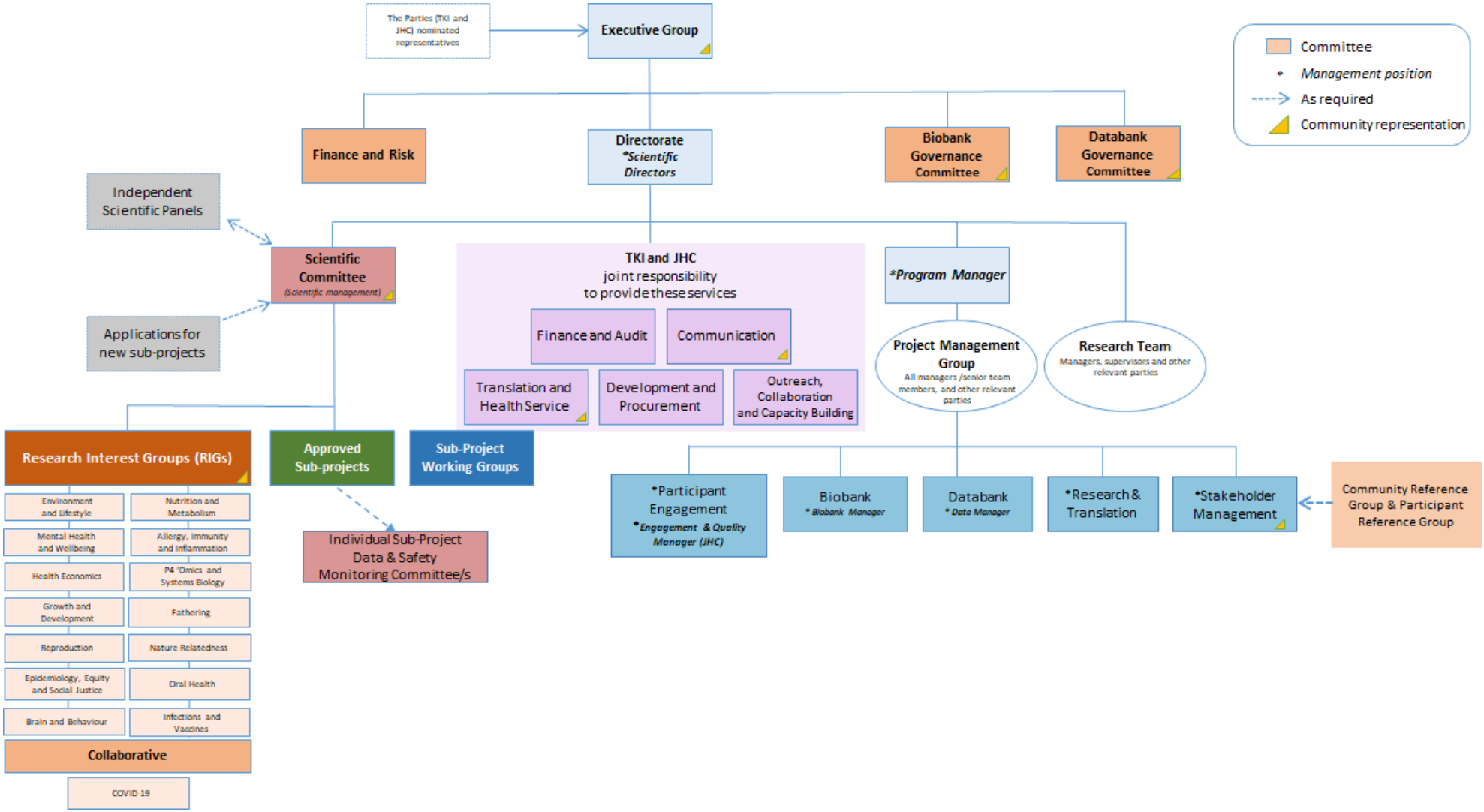

Figure 1.1. The ORIGINS Project Governance Structure.

2. PRINCIPLES OF ACCESS

- The ORIGINS Cohort and Database will be managed to optimise their utilisation and value for research and public benefit.
- Access to the ORIGINS Cohort and Database is achieved through the application and approval process outlined in this Policy.
- All applications to access, utilise or collect Data from the ORIGINS Cohort and Database should involve collaboration with ORIGINS Research Interest Group/s.
- Evidence of ethics and governance approval from the Joondalup Health Campus (JHC) Ramsay Health Care (RHC) Human Research Ethics Committee (HREC WA|SA) and other relevant Human Research Ethics Committees (HREC), along with any other relevant training and credentialing, is required prior to the commencement of all research activities and access to the ORIGINS Cohort and Database.
- A copy of all signed agreements relevant to the Researcher(s) application must be returned to The ORIGINS Project Management Group prior to commencement of all research activities and access to the ORIGINS Cohort and Database.
- Use of the ORIGINS Data for Commercial Purposes may be considered on a case-by-case basis, and subject to approval by the Directorate.
- It is a requirement that all Researchers comply with the *Australian Code for Responsible Conduct of Research*, the *NHMRC Management of Data and Information in Research Guidelines*, and relevant Telethon Kids Institute and JHC policies.
- The ORIGINS Project reserves the right to refuse or terminate access to the ORIGINS Cohort, Project Resources and/or Database in the case of a breach of this Policy, any signed agreements or the *Australian Code for the Responsible Conduct of Research* and/or *NHMRC Management of Data and Information in Research Guidelines*.

3. APPLICATION AND APPROVAL PROCESS

3.1 Expectations

The ORIGINS Project is a community resource that invites collaborative projects and initiatives, including those of students. All requests for access and/or use are encouraged from new Researchers, who work at one of the contributing Institutions (JHC or Telethon Kids), and from third-party Researchers who are external to Telethon Kids and JHC.

The expectations of all Researchers who wish to collaborate with ORIGINS are to:

- Support the vision, strategic imperatives and aims of ORIGINS
- Contribute their expertise and/or resources to advance ORIGINS
- Collaborate with Telethon Kids and JHC in relation to ORIGINS
- Collaborate with other Researchers involved with The ORIGINS Project
- Where possible, contribute towards The ORIGINS Project achieving its core aims
- Provide an agreed project contribution
- Include appropriate acknowledgement of The ORIGINS Project in all research promotion and dissemination
- Provide regular reports and feedback to ORIGINS, as requested
- Return all derived results, variables, feedback, samples, details of follow-up and Data (including biological, genetic and metadata) for the mutual benefit of future research

Researchers are:

- Responsible for compliance with relevant laws, regulations, and policies
- Responsible for securing their own independent funding, HREC and governance approval(s)
- Responsible for funding and financing all costs incurred in undertaking their research
- Autonomous and responsible for their own actions, behaviours, and activities

3.2 Feasibility, Acceptability and Planning

It is important that Researchers check the feasibility and acceptability of their proposed Sub-project through engagement with community members, Participants, The ORIGINS Project team, and other ORIGINS Researchers (**Figure 3.2**). Researchers are encouraged to engage community representatives independently or through the ORIGINS Community Reference Group and/or Participant Reference Group as early as possible in the planning of their Sub-project. Researchers may contact the ORIGINS Stakeholder Management to facilitate community and consumer engagement. In addition to the ORIGINS community and consumer engagement, new Researchers may establish their own (specific) Consumer and Community Reference Group(s).

Researchers planning to submit a Research Proposal must meet with relevant members of The ORIGINS Project Management Group to discuss feasibility, impact on clinical care at JHC, resource requirements (including clinician time and costs), Participant availability and commitments, Data and Biological Information availability, and costs associated with the proposed Sub-project.

Researchers should also achieve cross collaboration and harmonisation with ORIGINS, other current Sub-projects and Researchers. The ORIGINS Research and Translation Team can assist in linking new Researchers with existing Researchers working on related Sub-projects and the relevant Research Interest Group/s. Researchers planning to submit a Research Proposal must be an ORIGINS Research Interest Group member. It is recommended that potential Research Proposals are presented at a relevant Research Interest Group meeting.

3.3 Research Proposal Submission, Review and Approval

All new Sub-project applications require a completed *Research Proposal* (**Appendix A**) to be submitted to The ORIGINS Project Management Group and Scientific Committee for review and approval. This will allow The ORIGINS Project Management Group and Scientific Committee to assess:

- The viability and feasibility of the research (e.g., timeframe, available resources, budget)
- Any potential overlap with currently approved Sub-projects
- Whether the research questions, aims and objectives are consistent with the goals, vision and strategy of The ORIGINS Project
- Whether the methods and sample size are appropriate and justified
- Whether the number of Participants and/or volumes/biological samples requested are justifiable in terms of participant burden and impact to the finite ORIGINS Biobank
- If the research team are suitably qualified and experienced to implement the proposed Sub-project
- If there is sufficient community and consumer input

The scientific quality and originality of the Sub-project must be robust, such that the findings will be publishable, clinically relevant and contribute to knowledge. The research track record of the Chief Investigator must be sufficient to allow reasonable expectation that the research will be achieved and published successfully. All Research Proposals ***must include at least one member of the ORIGINS Scientific Committee or Project Management Group as an Investigator***. For governance purposes, it may also be necessary that a Joondalup Health Campus employee is included as an Investigator to be accountable for the research on site at Joondalup Health Campus.

Research Proposals are collated and reviewed by the Research and Translation Team for completeness prior to circulation to the Scientific Committee and Project Management Group for formal review. The Research and Translation Team will advise Researchers of

upcoming Scientific Committee meetings. All Research Proposals must be submitted at ***least two weeks*** before the date of the Scientific Committee meeting to be included in the meeting agenda. The Researcher is encouraged to attend and present at an upcoming Scientific Committee meeting. This allows for any queries, concerns or comments to be raised directly with the Researcher prior to/during review. Feedback will be provided to the Researcher within three weeks of the Scientific Committee meeting. The feedback from the Scientific Committee and Project Management Group may require a response and/or amendment to the Research Proposal and/or a second review by the Scientific Committee or Directorate. The Scientific Committee will identify if assessment by an Independent Scientific Panel, the ORIGINS Biobank Governance Committee or the ORIGINS Databank Governance Committee is required – should the Scientific Committee and Project Management Group determine it does not have sufficient expertise, identifies major conflicts of interest, or any other reason for independent assessment. Where a proposal seeks to access data that was collected by a Sub-project, the Scientific Committee (where feasible) will consult with the Researcher(s) who collected that data to ensure that the proposal makes appropriate use of that data.

In some instances, when only non-sensitive ORIGINS Data is requested, the Researcher may submit a Research Proposal that is reviewed and by the Project Management Group and Directorate, and approval can be provided by the Directorate on behalf of the Scientific Committee. In these instances, the Researcher will need to provide information at an upcoming Scientific Committee meeting and may be required to amend their Research Proposal if serious concerns are raised by the Scientific Committee.

If a Research Proposal is approved by the Scientific Committee and Project Management Group, or by the Directorate on their behalf, the Researcher will be provided with a letter of approval. If timing prohibits a full approval, as per the above processes, a provisional letter of approval from the Directorate may be requested (with two weeks' notice) to enable funding application submission(s).

3.4 Funding, Ethics and Governance

Following approval, the Researcher is entitled to commence funding application(s) and the process of obtaining HREC and governance approval. Funding must be confirmed for each new Sub-project. However, Research Proposals should be approved *before* external funding applications are made. Adequate professional, administrative, practical, and financial support and resources must be available to ensure successful completion of the Sub-project and integration with The ORIGINS Project. This must include adequate funds to cover ORIGINS administration and access fees (see **Section 4**). There is an expectation that Researchers cover the full cost of undertaking their Sub-project, including all ORIGINS administration and access fees.

The Researchers may apply to the RHC HREC WA|SA https://www.ramsayhealth.com.au/Research/Research-Ethics for ethics approval and in some circumstances corresponding governance approval https://www.ramsayhealth.com.au/Research/Research-Governance. It is recommended that Researchers state that their Sub-project is nested within The ORIGINS Project (ref

1440). We also suggest including a statement in the application/s and covering letter/s that the Sub-project has been reviewed and received approval from the ORIGINS Scientific Committee and Project Management Group. Alternatively, Researchers can obtain ethics approval from another appropriate HREC and governance committee. It is the responsibility of the Researchers to investigate and obtain the necessary HREC and governance approvals.

All approved HREC and governance applications including amendments, incidents, reports, and extensions are to be provided to the ORIGINS Research and Translation Team to be kept on file by The ORIGINS Project.

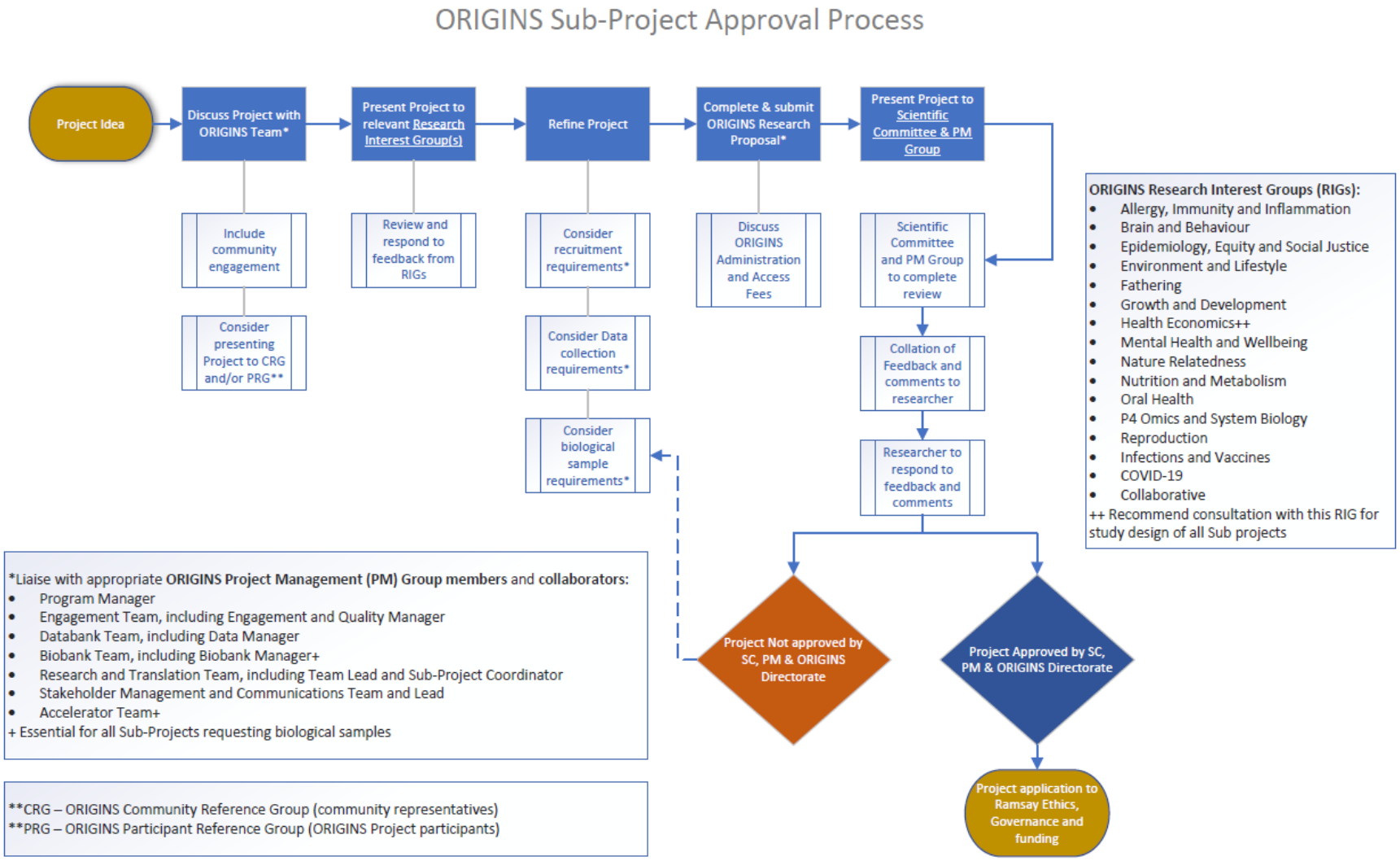

Figure 3.2. Flow diagram representing the application and approval process for new Researchers including new Sub-projects, grant applications and student projects.

4. AGREEMENT AND CONTRIBUTIONS

4.1 Sub-Collaboration Agreement and Letter Agreement

The overall framework for the implementation of The ORIGINS Project has been established by a Collaboration Agreement (*Collaboration Agreement*) between Telethon Kids Institute (Telethon Kids) and Joondalup Hospital Pty Ltd trading as Joondalup Health Campus (Joondalup Hospital). A *Sub-Collaboration Agreement* between Telethon Kids, Joondalup Hospital and external Researchers (*Sub-Collaboration Agreement*) has been established (**Appendix B**). Researchers who are internal employees of Telethon Kids or Joondalup Hospital are required to sign a *Letter Agreement* which includes a template version of the *Sub-Collaboration Agreement* as a schedule (**Appendix B**). A signed *Sub-Collaboration Agreement* or *Letter Agreement* must be executed for every Sub-project prior to accessing the ORIGINS Cohort, Project Resources, Biological Information and/or Database.

4.2 Project Contributions

There are significant economies of scale for conducting research within ORIGINS. The ORIGINS research platform only has core funding for establishment, management, and maintenance of the Cohort. Researchers will incur additional costs for administrative support, including participant recruitment, as well as extraction, collection, transfer and storage of Data and Biological Information.

A schedule of Project Contributions (**Appendix B**) will be attached to the *Sub-Collaboration Agreement* or *Letter Agreement*. The Project Contributions schedule includes details of the approved Sub-project including agreed duration (start and end date) taking into account resources and capacity of The ORIGINS Project team as well as overlap and timing of related ORIGINS Sub-projects. The Project Contributions schedule also includes details of the activities to be undertaken to procure the Sub-project, responsible Parties, contributions to be made by all Parties (financial or otherwise) and agreed due date(s) or timeframe. The Project Contributions schedule will be drafted in consultation with the Researcher(s).

Financial contributions will consist of an administration and access fee. The administration and access fee will be negotiated depending on the type and scale of the Sub-project and activities to be undertaken. Refer to the Fee Schedule (**Appendix C**) for a guide to costs.

5. ACCESS TO THE COHORT AND DATABASE

5.1 Requests to Access the Cohort and Database

The ORIGINS Project has an established Cohort and Database incorporating Biological Information and Participant Information from consented parents and children collected by Telethon Kids, JHC, and Researchers. The Researcher must ensure that all personnel with access to the ORIGINS Cohort and Database are made aware of their responsibilities, have read this Policy, and have signed the relevant agreement(s).

Researchers may request to access the Cohort and Database to: (1) implement a new clinical trial, intervention, or observational study; (2) collect new Data; (3) collect new Biological Information; (4) use existing Data; and (5) use existing Biological Information.

Access to the ORIGINS Cohort and Database is only permitted after completion of the following, as required:

- Approved Research Proposal (**Section 3**)
- Appropriate ethics and governance approval (**Section 3**)
- An executed *Sub-Collaboration Agreement/Letter Agreement* with Project Contributions (**Section 4**)
- Data Management Plan (**Section 5**)
- Data Sharing Agreement (**Appendix D**)
- Personnel credentialling (**Section 6**)
- Release of Biological Information form (**Appendix E**)
- Material Transfer Agreement (**Appendix F**)
- Relevant risk management documentation (**Section 6**)

Researcher(s) must ensure that if Data and/or Biological Information are located outside of WA, the location/s of all Data/Biological Information are specified fully in the *Research Proposal, Sub-Collaboration Agreement/Letter Agreement,* and *Release of Biological Information* form. Where the Chief Investigator is located outside of WA, the Sub-project requires a WA based nominated Co-Chief Investigator.

Cohort compliance with sample and data collection protocol is not guaranteed and the volume of available data does not directly correlate with participant numbers. Please contact the ORIGINS Research and Translation team for information on availability of data and samples suitable to your research.

5.2 Data Management Plan and Data Sharing Agreement

An initial data management planning meeting will be undertaken with representative(s) from The ORIGINS Project Management Group to develop a *Data Management Plan*. Two further meetings will be undertaken, half-way and at conclusion of the Sub-project, to

review and update the *Data Management Plan* as required. The *Data management Plan* will formalise for the Sub-project:

- Administrative details
- Re-using data
- Creating and collecting data
- Processing data
- Interpreting data
- Preserving data
- Giving access to data

The data management planning process is conducted through FAIR (Findability, Accessibility, Interoperability, Reusability) data management principles. It is important to undertake this to ensure a clear understanding of data collection, processing, and quality of Sub-project Data to guide Data return to the ORIGINS Database.

The *Data Sharing Agreement* outlines terms and conditions of use, storage, exchange and disposal of Data. This Agreement must be signed prior to any provision or contribution of Data.

5.3 Release of Biological Information

Researchers may request to access Biological Information for the purpose of laboratory analysis and/or for genetic studies. A *Release of Biological Information* form must be completed in consultation with the ORIGINS Biobank Manager. Biological samples from the ORIGINS Biobank are a finite resource and utilisation of these samples needs to afford the maximum benefit to ORIGINS Researchers and the wider research community. The feasibility of performing other analyses at the same time to maximise the value of the finite resources should be considered. The amount of sample requested must be justifiable in terms of its impact on the resource. Researchers are encouraged to make efforts to minimise the amount of Biological Information required. They must then ensure they are only requesting the minimum amount required for analyses. Use of the Biological Information will be carefully coordinated and controlled, because they are limited and depletable. Under certain circumstances, Biological Information may be released in batches with subsequent release dependent upon return of data from initial analyses. In some cases, the full volume of requested Biological Information may not be available to be released.

Requirements for the release of Biological Information include:

- Biological Information may only be used for the approved purposes and in accordance with the consent of ORIGINS Project Participants
- Biological Information will not be used for validation or optimisation analyses or to train personnel
- Any Biological Information that remains after analyses are complete must be returned to the ORIGINS Biobank in a usable form

- The methods of collection, processing, tracking, storage and analysis must be approved, validated and undertaken by trained personnel

The Executive will only approve physical release of Biological Information to Researchers who have completed the application process justifying the use of the Biological Information. Prior to receipt of the Biological Information, Researchers must complete a *Material Transfer Agreement*.

6. SUB-PROJECT IMPLEMENTATION AND ONGOING COMPLIANCE

6.1 ORIGINS Welcome and Implementation

The Sub-project implementation process commences with an ORIGINS welcome meeting(s) with relevant members of the ORIGINS team (**Figure 6.1**). Requirements, activities, contributions, logistics and expectations should be finalised for inclusion in the *Sub-Collaboration Agreement* or *Letter Agreement*. Following execution of the *Sub-Collaboration Agreement* or *Letter Agreement* and the initial payment of Project Contributions, the process of induction and orientation can commence. Induction and orientation involves all necessary training, credentialing and compliance checks (see **Section 6.2**). Prior to commencement of the Sub-project, and as an ongoing requirement of The ORIGINS Project, certain documentation is required to be provided to the Research and Translation Team. This may include (as relevant) but not be limited to:

- Ethics and governance submissions, reports, and approvals
- Funding submissions, reports, and approvals
- Other agreements or contracts
- Project protocol
- Participant documents
- Project plan
- Data management plan
- Communication plan
- Risk management documentation
- Quality, data and safety monitoring documentation
- Research dissemination (see **Section 7**)

Where required and requested, templates can be provided by The ORIGINS Project for the Researcher's use.

Any Sub-project amendments such as a change to team members, research activities, protocol or timeline must go through the ORIGINS review and approval process as per **Section 3.3** and amended/further documentation (as listed above) is to be provided to the Research and Translation Team. Sub-project amendments may also require an updated or additional Project Contributions schedule to be agreed and signed by all Parties.

6.2 Training and Credentialing

All personnel involved in the Sub-project that intend to have direct contact with the ORIGINS Cohort, Data and/or Biological Information must undergo the required inductions and orientation. This will include necessary training, credentialling and compliance checks. Sub-project team members that intend to have direct contact with the ORIGINS Cohort require more extensive training and credentialing. The necessary training and credentialing will be initiated and guided by The ORIGINS Project personnel and may include (as relevant) but not be limited to:

- Compliance with policies
- Relevant health requirements including immunisation
- Emergency procedure training
- Site access and induction
- Access to shared folders, ShareFile and/or database(s)
- Good Clinical Practice training
- Working with Children Check
- National police clearance/Fit2 work clearance

The Chief Investigator must provide ongoing and updated information on the status of training and credentialing for all personnel involved in the Sub-project.

6.3 Ethics and Governance

Copies of the following ethics and governance documents must be provided to The ORIGINS Project via the Research and Translation Team:

- Human Research Ethics Applications
- Amendments, notifications, and changes
- Annual reports
- Other agreements or contracts relevant to the Sub-project
- Sub-project study items such as consent forms, withdrawal forms and participant information brochures
- Grant and/or funding applications

The Chief Investigator must notify the Research and Translation Team, and all HREC Committees, of any changes to their Sub-project, including but not limited to changes in the list of Researchers or personnel utilising the ORIGINS Cohort, Data and/or Biological Information, changes in the research protocol, security arrangements or location of the research Data or any derivatives. Sub-project's changes may require the submission of a summary of changes, revised Research Proposal, and review by the Project Management Group, Scientific Committee, Directorate, ORIGINS Program Manager and/or ORIGINS Team Leads.

6.4 Risk Management and Data Safety Monitoring

Sub-projects that include an intervention are expected to undertake their own Clinical Research Risk Assessment and share relevant documents with the Research and Translation Team prior to initiation. This documentation should include a list of the key risks for the Sub-project, and a description of how the study team plans to identify, analyse, and prioritise risks. ORIGINS also require specific details of the methods used for tracking risks and incidents and any mitigation plans in place. Randomised controlled trials (interventional) are responsible for their own adverse event reporting, as per HREC requirement for their Sub-project, but must share any associated documentation with the Research and Translation Team in a timely manner.

Non-interventional Sub-projects (observational) must provide the ORIGINS Research and Translation Team with relevant quality and safety monitoring documentation. This must include documentation for monitoring and managing ongoing risks and incidents (e.g., risk management plan and/or risk register) and notification of any incidents, accidents, or breaches.

All Sub-projects must provide the ORIGINS Data Manager with a copy of their *Data Management Plan* and *Data Sharing Agreement* (see **Section 5.2**).

6.5 Reporting and Attendance

The Chief Investigator must provide the ORIGINS Program Manager with an annual update on the progress of the Sub-project, a final report at the completion of the Sub-project, and as requested quarterly updates during the Sub-project. For example, quarterly or monthly reporting may be required, as stipulated within the *Sub-Collaboration Agreement/Letter Agreement* and Project Contributions. Attendance at the quarterly ORIGINS Sub-project meetings is required by a Sub-project representative.

6.6 Project Contributions

Activities and payment(s) (e.g., administration and access fees) must be undertaken and provided in accordance with the agreed Project Contributions set out in the *Sub-Collaboration Agreement/Letter Agreement*. Further Project Contributions may also be agreed to and signed off by all Parties during the course of the Sub-project.

6.7 Sub-project Acquittal

At the completion of a Sub-project (i.e., completion of all activities) The ORIGINS Project requires documentation outlining project completion (final report) and acquittal of all outstanding payment(s) and Project Contributions. The ORIGINS Project may request some feedback and an evaluation.

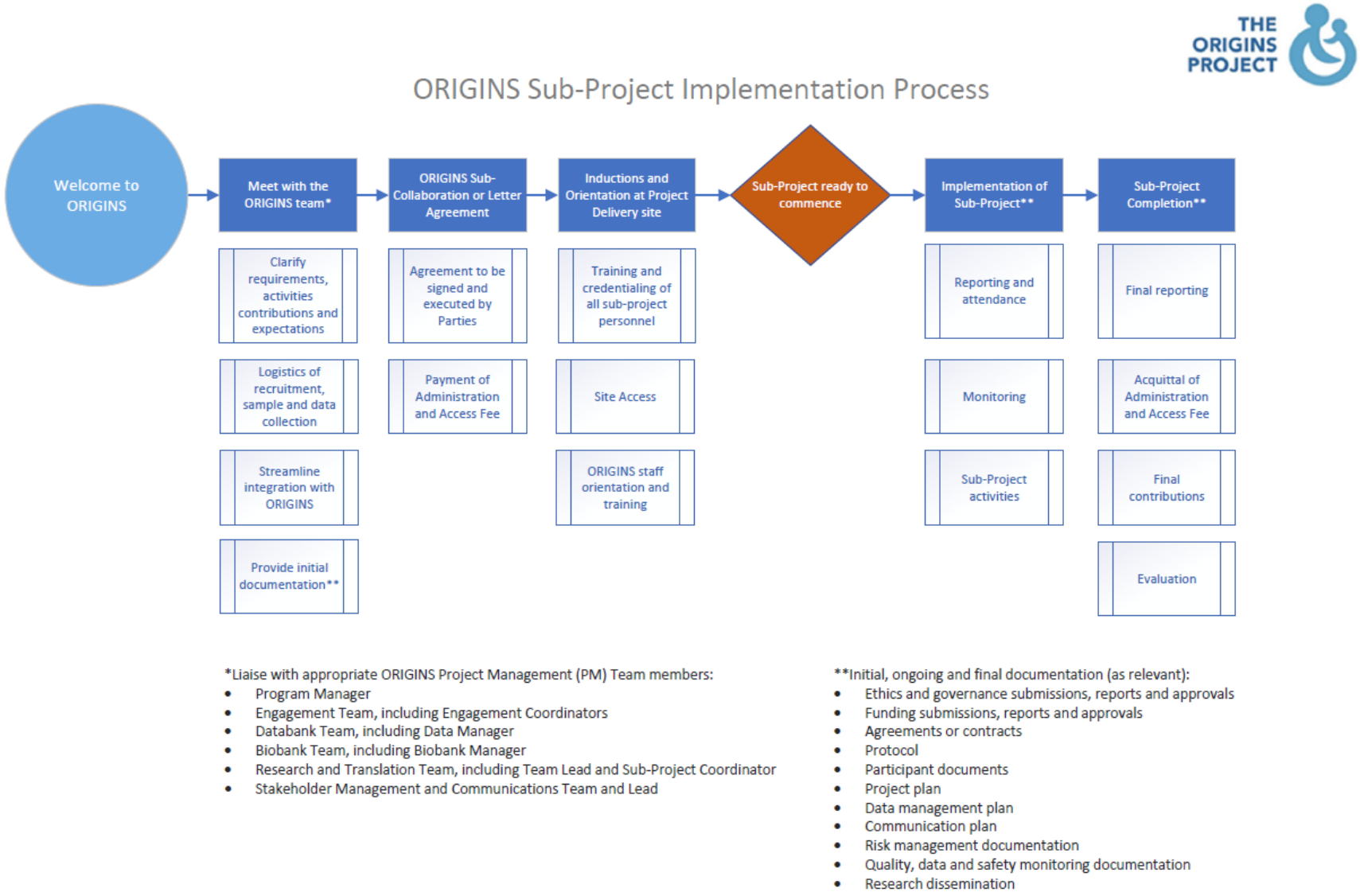

Figure 6.1. ORIGINS Sub-project Implementation Process.

7. RESEARCH DISSEMINATION

7.1 Research Dissemination Review and Approval

There is a requirement of all Researchers to place the findings (whether positive or negative) from all research based on the ORIGINS Cohort and/or Database in the public domain. Any form of dissemination of findings (including but not limited to publications, media or presentations) must be submitted to the ORIGINS Research and Translation Team for review and approval prior to submission for publication, presentation or release. The dissemination or communication will be reviewed by The ORIGINS Project Management Group for:

- Scope
- Authorship
- Acknowledgments
- To ensure no overlap or conflict with other dissemination or communication
- To confirm internal consistency of reporting (e.g., sample size, data collection methods)
- To confirm protection of confidentiality.

If a manuscript requires substantial author corrections, or the authors substantially modify the content to submit to a different journal, this manuscript review and approval process needs to be repeated for the modified manuscript.

Advice and feedback will be offered to authors where it is deemed this may be helpful. Final written approval from the ORIGINS Research and Translation Team must be obtained prior to publication or dissemination. The ORIGINS Project does not, however, accept scientific responsibility for the content of publications or presentations from Researchers.

The general ORIGINS policy is that there is a media embargo until a paper is published. Some journals have very strict media policies. Publicity can jeopardise the publication of papers if this contravenes the journal's policy. If there are circumstances where this is potentially unavoidable, e.g. conference organisers requesting media statements, any publicity should have the written approval of all the authors and the ORIGINS Research and Translation Team.

When a final manuscript, presentation or release is accepted for publication or made public, the Chief Investigator must submit an electronic copy of the published version to the ORIGINS Research and Translation Team. Publications arising from the use of the Cohort, Database and/or Biological Information will be listed on The ORIGINS Project website.

To further improve research dissemination outcomes, the Chief Investigator or lead/corresponding author of the published paper will be asked to write a Nutshell report, to be uploaded to the ORIGINS website, summarising the aims and findings of the paper in lay terms. Alternatively, the researcher can select for an ORIGINS student to create a nutshell report which the researcher will approve before it goes online.

7.2 Authorship and Acknowledgment

Publication authorship must be consistent and follow standard practice journal regulations and requirements that all authors must have made a substantial contribution to the conception and design of the Sub-project, or analysis and interpretation of data, and drafting the paper. In a study such as The ORIGINS Project there is likely to be several people whose work makes production of a paper possible but who may not meet authorship criteria. In such cases we encourage the inclusion of contributorship as per BMJ guidelines https://www.bmj.com/about-bmj/resources-authors/article-submission/authorship-contributorship.

All research dissemination from the Sub-project should clearly acknowledge the contribution from the Joondalup/Wanneroo community. The cohort study has been set up to attempt genuine public engagement and The ORIGINS Project Cohort should therefore be seen as active contributors, rather than just passive Participants. The following standard acknowledgement must be included in all instances of dissemination of findings using ORIGINS Data:

"We are grateful to all the ORIGINS families who support the project.

We would also like to acknowledge and thank the following teams and individuals who have made The ORIGINS Project possible: The ORIGINS Project team; Joondalup Health Campus (JHC); members of ORIGINS Community Reference and Participant Reference Groups; Research Interest Groups and the ORIGINS Scientific Committee; Telethon Kids Institute; City of Wanneroo; City of Joondalup; and Professor Fiona Stanley."

The following funding acknowledgement statement should be included in all papers accessing and/or using the ORIGINS Cohort, Data and/or Biological Information:

"The ORIGINS Project has received core funding support from the Telethon Perth Children's Hospital Research Fund, Joondalup Health Campus, the Paul Ramsay Foundation and the Commonwealth Government of Australia through the Channel 7 Telethon Trust. Substantial in-kind support has been provided by Telethon Kids Institute and Joondalup Health Campus."
If referring to the biobank, refer to it as the ORIGINS Project Biobank. The above acknowledgements should be included, as presented here, in all dissemination of findings. In addition, the following publication should be referenced when referring to the ORIGINS biobank:

> D'Vaz, N., Kidd, C., Miller, S., Amin, M., Davis, J. A., Talati, Z., Silva, D. T., & Prescott, S. L. (2023). The ORIGINS Project Biobank: A Collaborative Bio Resource for Investigating the Developmental Origins of Health and Disease. International Journal of Environmental Research and Public Health, 20(13),. https://doi.org/10.3390/ijerph20136297

As required, the ORIGINS Research and Translation Team can provide further advice to authors on specific individuals who played a key scientific role in the generation and/or collection of Data and/or Biological Information.

7.3 Identification

It is important that all work linked to The ORIGINS Project is easily identified, including in electronic searches. We ask Researchers to include *The ORIGINS Project or ORIGINS sub-project* in article titles, e.g. Fertility in a prospective birth cohort: an ORIGINS sub-project. If this is not possible then authors must include *The ORIGINS Project* as a keyword and in the abstract.

All outputs and work or media generated by the Sub-project should clearly acknowledge the study as a Sub-project of ORIGINS, as follows:

" This study is a sub-project of The ORIGINS Project. This unique long-term study, a collaboration between Telethon Kids Institute and Joondalup Health Campus, is one of the most comprehensive studies of pregnant women and their families in Australia to date, recruiting 10,000 families over a decade from the Joondalup and Wanneroo communities of Western Australia."

7.4 Use of The ORIGINS Project Logo and Assets

The ORIGINS Project tri-logo lock up should be used to acknowledge the Sub-project's involvement. The ORIGINS symbol is part of a tri-logo lock up and sits alongside the Telethon Kids Institute and Joondalup Health Campus logos, acknowledging our collaborators. It ***should not be used*** without this logo lock up, unless consultation is undertaken with The ORIGINS Project Management Group.

Click HERE to download a jpeg of The ORIGINS Project tri-logo lock up for use. The logo should be used in full colour wherever possible, but can be used in all black or all white if necessary. No alternative shades or colours should be used. The main brand colours of The ORIGINS Project are PMS 284 (light blue) and PMS 7683 (dark blue). It is not necessary for Sub-projects to use these colours in their materials.

ORIGINS imagery, photos, graphics, website content and other assets should not be used without permission from The ORIGINS Project Management Group.

7.5 Intellectual Property

JHC and Telethon Kids hold joint ownership and Intellectual Property of the ORIGINS Cohort and Database. The ownership and use of Intellectual Property created as a result of approved Research Proposals will be governed by the terms of this Policy and the *Sub-Collaboration Agreement/Letter Agreement* together with the terms of any applicable Licence Agreement, Commercialisation Agreement or other agreement entered into in relation to that Research Proposal. The Executive will advise on any apportionment of Intellectual Property resulting from access to the ORIGINS Cohort or Database. As a general principle, the Executive will determine the use of Intellectual Property on behalf of the owners.

8. APPENDICES

A. Research Proposal

B. Sub-Collaboration Agreement/Letter Agreement and Project Contributions

C. Fee Schedule

D. Data Sharing Agreement

E. Release of Biological Information form

F. Material Transfer Agreement