ORIGINS
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
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2021-01-13	Version 8
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2025-11-18	Version 10

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]

ORIGINS is a collaborative initiative between The Kids Research Institute Australia (The 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'.

ORIGINS 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 Participant Information).
- Use of existing Data (Biological Information and 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 ORIGINS 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 ORIGINS.
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 ORIGINS.
5. "Collaboration Agreement" means the agreement entered into between The Kids and JHC in respect of ORIGINS.
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. Academic research sponsored by industry is not considered a use of the data for Commercial Purposes, unless it involves any of the activities listed above.
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 ORIGINS 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 ORIGINS Executive Group, comprising an equal number of representatives nominated from both parties: The Kids and Joondalup Health Campus. The Executive is responsible for overseeing the activities, objectives, implementation, and obligation of ORIGINS 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 ORIGINS by providing Biological Information and Participant Information.
17. "Party" means any of The 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 Directorate, Data Manager, Biobank Manager, Paediatric Team Coordinator, and Stakeholder Management Team Lead. It also includes representative from Joondalup Health Campus.
21. "Project Resources" means resources (such as financial, staff, premises, consumables, or facilities) required for the purposes of enabling ORIGINS to be implemented.
22. "Research Proposal" refers to the formal proposal submitted by Researcher(s) for consideration of access and/or use of the Cohort and/or Database.
23. "Researcher(s)" refers to the **Chief Investigator (CI)**, who is the primary point of contact and accountability for any collaboration with ORIGINS. The CI is responsible for ensuring that all team members involved in the research are properly informed about this policy, complete any required training, and comply with ORIGINS governance requirements.
24. "Scientific Committee" comprises representatives from multiple research domains, the major tertiary institutions in WA, ORIGINS Directorate, and at least one clinical representative of Joondalup Health Campus.
25. "Sub-project" refers to a nested research project/study that is incorporated into and/or connected to ORIGINS 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 website https://originsproject.thekids.org.au/ It is the responsibility of the Researchers to be aware of and adhere to any changes.

All enquiries should be directed to ORIGINS Research and Translation Team ORIGINS.Research@thekids.org.au.

CONTENTS

LIST OF FIGURES

1. ORIGINS

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

ORIGINS governance structure **(Figure 1)** has been established to outline the relationships between all organisational levels and ensure accountability from all relevant parties.

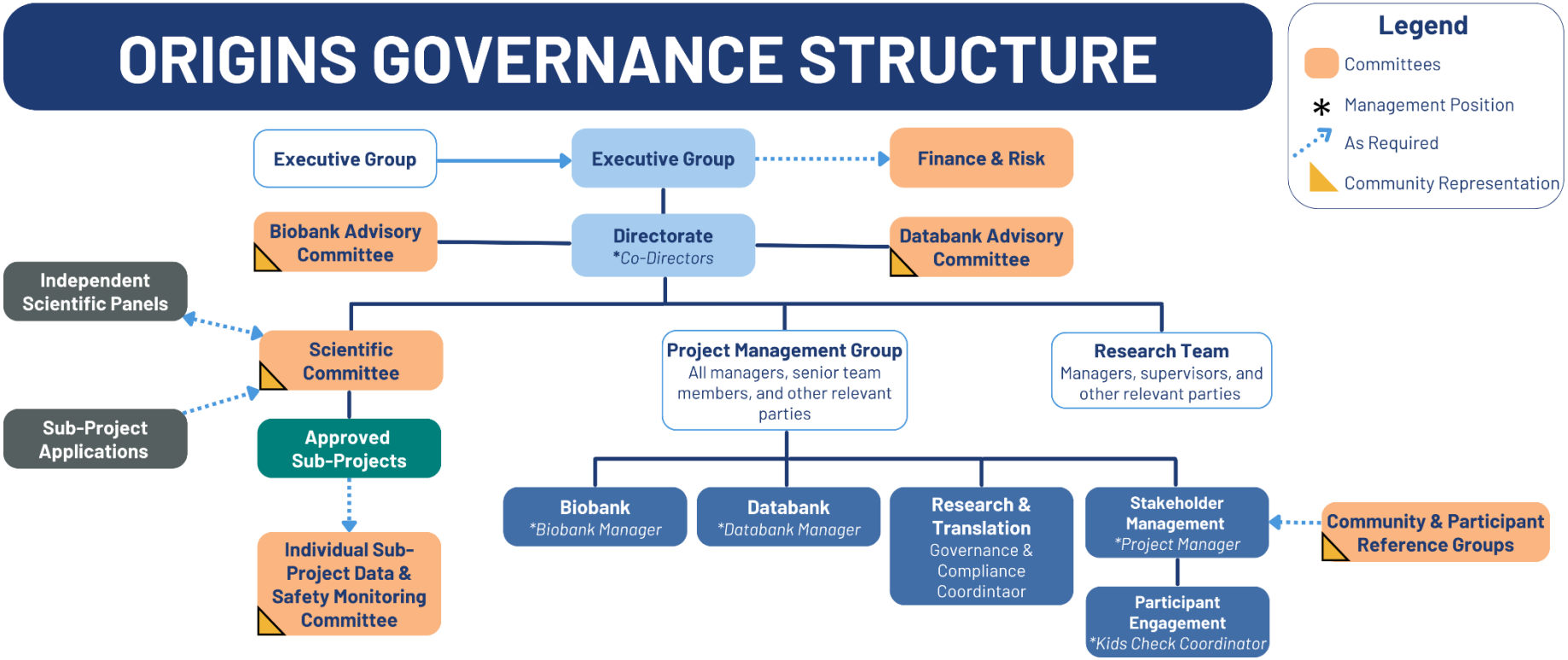

Figure 1: ORIGINS Governance Structure

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.
- Evidence of ethics and governance approval, along with any relevant training and credentialing, is required prior to the commencement of all research activities and access to the ORIGINS Cohort and Database. This approval may be obtained from the Joondalup Health Campus (JHC) Ramsay Health Care (RHC) Human Research Ethics Committee (HREC WA|SA) or from a National Health and Medical Research Council (NHMRC)-registered HREC.
- All signed agreements relevant to the Researcher(s) application must be submitted to ORIGINS 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 The Kids and JHC policies.
- ORIGINS 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

ORIGINS is a community resource that invites collaborative projects and initiatives, including student-led research. Requests for access and use are encouraged from Researchers, who work at one of the contributing Institutions (JHC or The Kids) as well as external Researchers.

Researchers collaborating with ORIGINS are expected to:

- Support the vision, strategic imperatives and aims of ORIGINS
- Contribute expertise and/or resources to advance ORIGINS objectives
- Collaborate with The Kids and JHC in relation to ORIGINS
- Collaborate with other Researchers involved with ORIGINS
- Provide an agreed project contribution and acknowledge ORIGINS in all research outputs
- Submit regular reports and updates as requested
- Return derived results, data, samples, and feedback for the mutual benefit of future research

Researchers are also responsible for:

- Complying with all relevant laws, regulations, and institutional policies
- Securing their own funding, ethics and governance approval prior to commencing research
- Covering all costs associated with their project
- Maintaining professional integrity and accountability for their actions and research activities

3.2 Feasibility, Acceptability and Planning

Researchers should confirm the feasibility and acceptability of their proposed Sub-project through engagement with community members, Participants, ORIGINS team, and other ORIGINS Researchers (**Figure 2**). Early engagement with community representatives, either independently or through the ORIGINS Community Reference Group and/or Participant Reference Group, is strongly encouraged. Researchers may contact ORIGINS Stakeholder Management to facilitate community and consumer engagement, or choose to establish their own Consumer and Community Reference Group(s).

Researchers planning to submit a Research Proposal must meet with relevant members of 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.

3.3 Research Proposal Submission, Review and Approval

All new Sub-project applications must include a completed *Research Proposal* (**Appendix A**) submitted to the ORIGINS Scientific Committee and Project Management Group for review and approval. This will allow both groups 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 ORIGINS
- 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, a JHC employee may need to be included as an Investigator to ensure accountability for research conducted on-site.

Research Proposals are first checked by the Research and Translation Team for completeness prior to circulation to the Scientific Committee and Project Management Group for formal review.

Researchers will be informed of upcoming Scientific Committee meeting dates and must submit proposals at least ***two weeks prior*** to be included on the agenda. Researchers are encouraged to attend and present at the meeting to address questions directly.

Feedback will be provided within three weeks of the meeting and may include requests for amendments or a second review. If additional expertise is required, the Scientific Committee may refer proposals to an Independent Scientific Panel or relevant ORIGINS Governance Committees. Where a proposal seeks access to data collected by an existing Sub-project, the Scientific Committee will consult with the original Researcher(s) where possible.

For proposals requesting non-sensitive ORIGINS Data, review may be completed by the Project Management Group and Directorate, with approval granted by the Directorate

on behalf of the Scientific Committee. In these cases, Researchers must still provide information at a future Scientific Committee meeting and respond to any concerns raised.

Once approved, Researchers will receive a **provisional Letter of Approval**. A full Letter of Approval will be issued upon receipt of all essential documents outlined in the provisional approval letter.

3.4 Funding, Ethics and Governance

Following approval, the Researcher may commence funding applications. Funding must be confirmed for each new Sub-project. Adequate professional, administrative, practical, and financial resources must be available to ensure successful completion of the Sub-project and its integration with ORIGINS. This includes adequate funds to cover ORIGINS administration and access fees. Researchers are expected to meet the full cost of undertaking their Sub-project.

Researchers may apply to the RHC HREC WA|SA https://www.ramsayhealth.com.au/Ramsay-Research/Reseach-Ethics-at-Ramsay for ethics approval and in some circumstances corresponding governance approval https://www.ramsayhealth.com.au/Ramsay-Research/Applying-for-Research-Governance-at-Ramsay.

It is recommended that Researchers state that their Sub-project is nested within ORIGINS (Ref 1440) and provide the provisional approval letter from ORIGINS confirming that the Sub-project has been reviewed and approved by the ORIGINS Scientific Committee and Project Management Group. Alternatively, Researchers may seek ethics approval from any NHMRC-registered HREC and the relevant governance committee. It is the responsibility of Researchers to investigate and obtain all 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 ORIGINS.

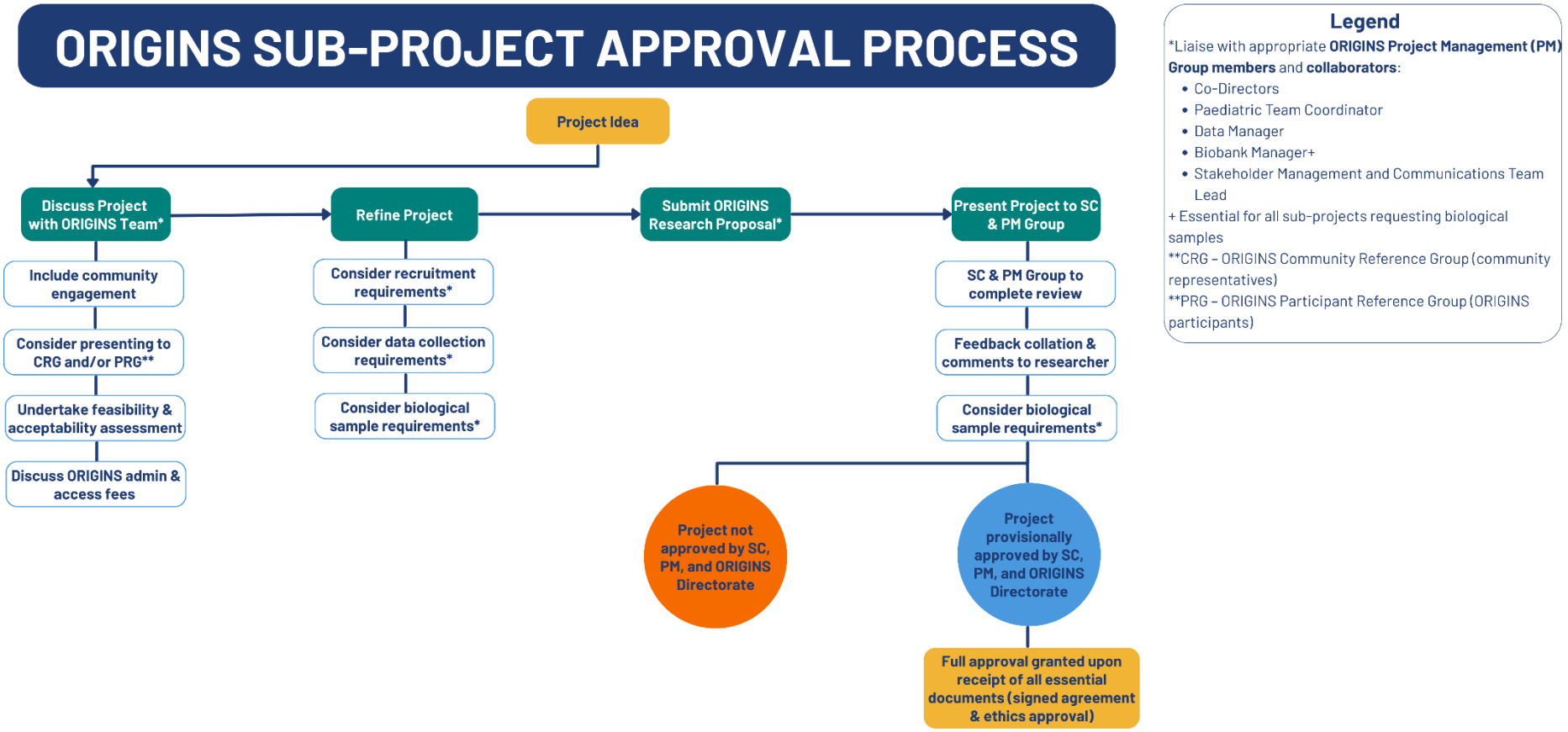

Figure 2: Flowchart showing the application and approval process for new Sub-projects and student projects

4. AGREEMENT AND CONTRIBUTIONS

4.1 Sub-Collaboration Agreement and Letter Agreement

The overall framework for the implementation of ORIGINS has been established by a Collaboration Agreement (*Collaboration Agreement*) between The Kids and Joondalup Hospital Pty Ltd trading as Joondalup Health Campus (Joondalup Hospital). A *Sub-Collaboration Agreement* between The Kids, Joondalup Hospital and external Researchers (*Sub-Collaboration Agreement*) has been established. Researchers who are internal employees of The Kids or Joondalup Hospital are required to sign a *Letter Agreement* which includes a template version of the *Sub-Collaboration Agreement* as a schedule. 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

ORIGINS is a not-for-profit research platform with core funding allocated for establishment, management, and maintenance of the Cohort. To ensure sustainability and cost recovery, additional costs associated with Sub-project will be borne by the Researchers. These costs may include administrative support, participant recruitment, and the extraction, collection, transfer, and storage of Data and Biological Information.

A Project Contributions Schedule will be attached to the *Sub-Collaboration Agreement* or *Letter Agreement*. The Project Contributions schedule includes:

- Details of the approved Sub-project, including agreed start and end dates, taking into account resources and capacity, as well as overlap with other Sub-projects.
- Activities required to deliver the Sub-project, responsible Parties, contributions (financial or in-kind) from all parties.
- Agreed due date(s) or timeframes for Project Contributions.

Financial contributions will consist of an administration and access fee, negotiated based on the type and scale of the Sub-project and activities to be undertaken. Please refer to the Fee Schedule (**Appendix B**) for indicative costs.

5. ACCESS TO THE COHORT AND DATABASE

5.1 Requests to Access the Cohort and Database

ORIGINS has an established Cohort and Database incorporating Biological Information and Participant Information from consented parents and children collected by The Kids, JHC, and Researchers. The CI 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**)
- A fully executed *Sub-Collaboration Agreement/Letter Agreement* with Project Contributions (**Section 4**)
- Data Management Plan (**Section 5**)
- CI credentialling (**Section 6**)
- Access to Data Form **(Appendix C)**
- Release of Biological Information form (**Appendix D**)
- Material Transfer Agreement (**Appendix E**)
- Relevant risk management documentation (**Section 6**)

Researchers must specify the location of all Data and/or Biological Information in the *Research Proposal, Sub-Collaboration Agreement/Letter Agreement, Access to Data Form or DMP* and *Release of Biological Information* form, particularly if stored outside WA. Storage in other Australian States is permitted under the Privacy Act, provided institutional policies are followed. Where storage occurs outside Australia, appropriate privacy and security measures must comply with the Australian Privacy Act and relevant institutional requirements.

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

An initial data management planning meeting will be undertaken with ORIGINS Data Manager to develop a *Data Management Plan* (DMP). The DMP 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.

5.3 Release of Biological Information

Researchers may request Biological Information for laboratory or for genetic analyses by completing a *Release of Biological Information Form* **(Appendix D)** with the ORIGINS Biobank Manager. As samples are a finite resource, requests must be justified and limited to essential amounts. Access will be coordinated and may occur in batches, with subsequent releases dependent on data return. Full requested volumes may not always be available.

Requirements for the release of Biological Information:

- Biological Information may only be used for approved purposes and in accordance with the consent of ORIGINS Participants
- It must not be used for validation or optimisation, or personnel training
- Any remaining Biological Information analyses must be returned to the ORIGINS Biobank in a usable form
- Collection, processing, tracking, storage and analysis must be approved, validated and undertaken by trained personnel

ORIGINS Biobank Manager will coordinate the release of Biological Information to Researchers who have completed the application process and justified the use of the Biological Information. The Biobank Manager will inform the ORIGINS Directorate of the request, and in some cases, an independent expert review may be sought to provide advice on whether samples can be released. Prior to receipt of the Biological Information, Researchers must complete a *Material Transfer Agreement*.

5.4 Data Usage, Retention and Accessibility

Exclusive Access Period

Researchers approved for a Sub-project have exclusive use of the dataset for the duration specified in the Sub-Collaboration Agreement or Letter Agreement (maximum 3 years unless otherwise agreed). After this period, data may be made available to other

researchers unless an extension is requested and approved by the ORIGINS Scientific Committee.

Extension requests must be submitted at least 1 month before project expiry, with justification and an updated timeline. If another researcher requests access to the same dataset during the exclusive period, ORIGINS may offer collaboration opportunities.

Active Use of Data

Researchers must actively use the data following acquisition. If no substantial progress is demonstrated within 6 months, exclusive access may be revoked. Researchers will be notified and given 30 days to respond before data is reassigned.

Data Return

All generated data must be returned to the ORIGINS platform within 6 months of completing data analysis, as outlined in the agreement. Original datasets provided by ORIGINS must be deleted from all devices once used for approved research activities.

Absence of Chief Investigator

The CI must notify ORIGINS at least 30 days before extended leave and designate an alternate contact to manage data. If no alternate is available, ORIGINS will retrieve data from other team members.

Time-Sensitive Requests & Escalation

If data is urgently required and the CI cannot be reached after two formal notifications, ORIGINS will escalate to senior representatives (e.g., ORIGINS Executive Group, Institute Director of Research). Continued non-compliance may result in legal action, including breach of contract claims.

6. SUB-PROJECT IMPLEMENTATION AND ONGOING COMPLIANCE

6.1 ORIGINS Welcome and Implementation

Sub-project implementation process (**Figure** 3) commences once:

- All essential documents outlined in the provisional Approval Letter have been provided to the ORIGINS Research and Translation Team
- Training and credentialing of the CI
- Payment of fees as outlined in the Sub-Collaboration Agreement or Letter Agreement has been received

Essential documentation may include, but is not 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

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

Upon completion of these prerequisites, an ORIGINS Welcome Meeting will be arranged with ORIGINS Research & Translation Team. During this meeting, the team will:

- Review and confirm the Data and Biological Information extraction
- Discuss key obligations, including attendance at sub-project meetings
- Outline reporting requirements, such as submitting biannual progress reports via REDCap and completing surveys.

Following the Welcome Meeting, the Sub-project will be officially initiated.

6.2 Training and Credentialing

ORIGINS requires the CI to complete all necessary credentialing and training prior to the Welcome Meeting. ORIGINS does not credential other Sub-project personnel; however, the CI must ensure that all Sub-project personnel are appropriately trained, qualified and informed of ORIGINS policies and requirements.

All personnel who will have direct contact with the ORIGINS Cohort, Data and Biological Information must complete in but not be limited to:

- Compliance with ORIGINS and The Kids policies
- Good Clinical Practice training
- Working with Children Check (WWCC) – mandatory under WA law for any Sub-project personnel with face-to-face interaction with children during any activities conducted in The Kids site
- Access to shared folders, ShareFile and/or database(s)
- National police clearance/Fit2 work clearance
- Emergency procedure training
- Site access and induction

ORIGINS will guide the credentialing process for the CI and collect their certificates and required documentation. The CI is responsible for:

- Completing their own credentialing and training
- Ensuring team members meet all legal, ORIGINS and institutional requirements, relevant training, including WWCC where applicable
- Communicating policy updates and process changes to the team, as ORIGINS will notify the CI via meetings and email

6.3 Ethics and Governance

Copies of the following ethics and governance documents must be provided to ORIGINS 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 final applications

The CI must notify the Research and Translation Team and all HREC Committees of any changes to the Sub-project. This includes, but is not limited to:

- Changes in the list of researchers or personnel accessing ORIGINS Cohort, Data, or Biological Information
- Changes to the research protocol
- Changes to security arrangements or data storage location

Any Sub-project amendments, such as changes to team members, research activities, protocol, or timeline, must be reported to the ORIGINS Research and Translation Team.

Depending on the scale of the request, a variation may require additional review by ORIGINS Scientific Committee and Project Management Group by submitting a Variation Request Form **(Appendix F)**.

Once the variation is approved, the existing Sub-collaboration Agreement or Letter Agreement must be updated and fully executed before any changes can be implemented.

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*.

6.5 Reporting and Attendance

The CI must provide the ORIGINS Research & Translation Team with biannual progress update on the Sub-project via REDCAP survey. A Sub-project representative is also required to attend ORIGINS Sub-project meetings three times per year.

6.6 Project Contributions

Activities and payment(s) (e.g., administration and access fees) must be carried out in line with the agreed Project Contributions set out in the *Sub-Collaboration Agreement* or *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) ORIGINS requires documentation outlining project completion (final report) and acquittal of all outstanding payment(s) and Project Contributions. ORIGINS may request some feedback and an evaluation.

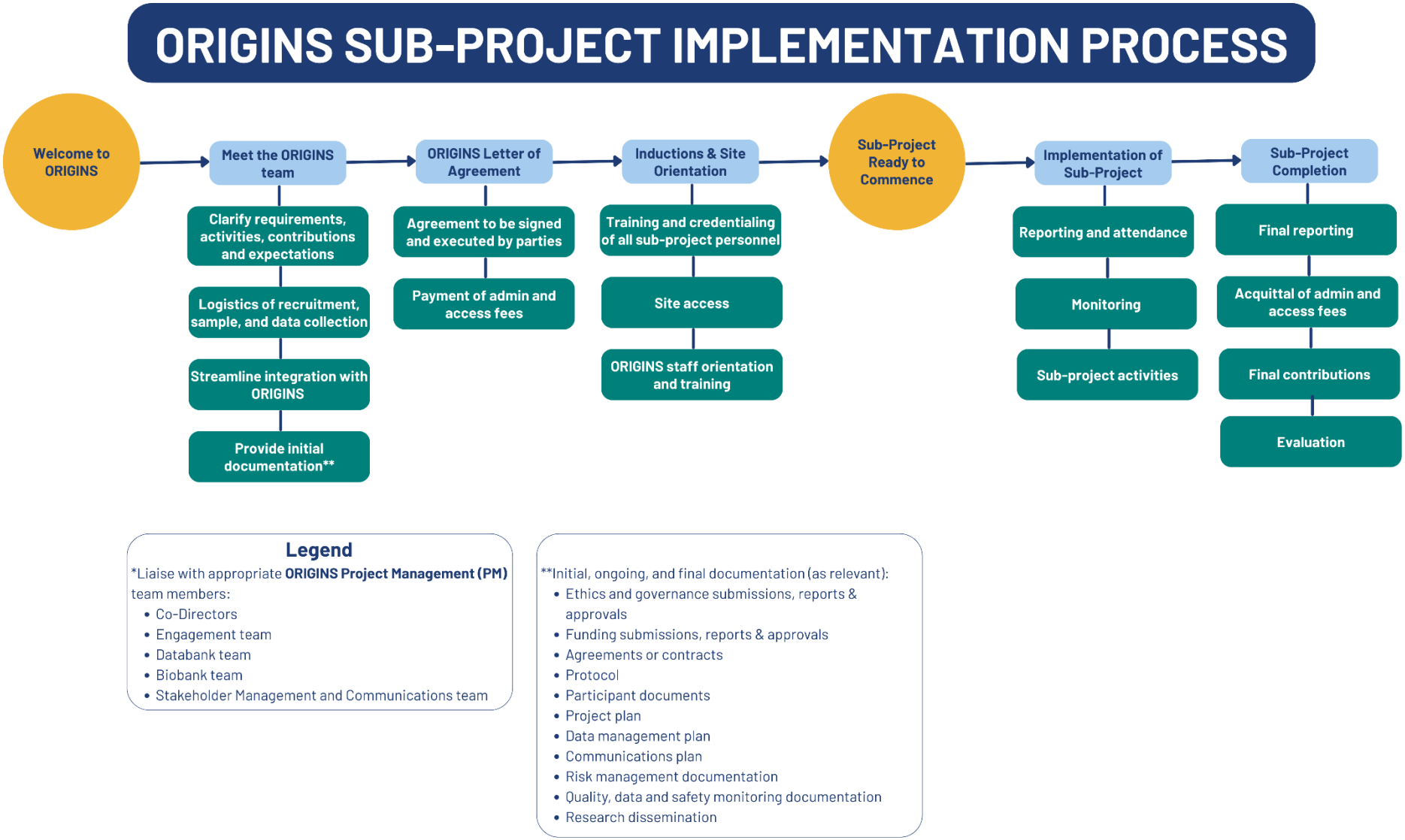

Figure 3: ORIGINS Sub-project Implementation Process

7. RESEARCH DISSEMINATION

7.1 Research Dissemination Review and Approval

All Researchers are required to make findings (whether positive or negative) from any research based on the ORIGINS Cohort and/or Database publicly available. All outputs (including but not limited to manuscripts, datasets, media releases) must be submitted to the ORIGINS Research and Translation Team for review and approval prior to submission for publication, presentation or release. Dissemination and 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 undergoes major revisions, or is resubmitted to a different journal, the ORIGINS review and approval process will be repeated. Advice and feedback will be offered to authors where helpful and final written approval from the ORIGINS Research and Translation Team must be obtained prior to publication or dissemination. ORIGINS does not, assume scientific responsibility for the content of publications or presentations.

ORIGINS policy includes a media embargo until a paper is published. Some journals have strict media rules and early publicity can jeopardise acceptance. If publicity is unavoidable, (e.g. conference organisers requesting media statements), a written approval from all the authors and the ORIGINS Research and Translation Team is required.

Once a manuscript, presentation, or release is accepted for publication or made public, the CI must submit an electronic copy of the final 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 website.

To improve research dissemination, the CI or lead author will be asked to write a Nutshell summary in lay terms for the ORIGINS website.

7.2 Public Data Repository Submissions

Researchers intending to submit ORIGINS data to public data repositories (e.g., to meet journal requirements) must obtain prior approval from the ORIGINS Data Manager before any upload or submission takes place.

Data **must not** be uploaded to any public platform without this review and approval.

Failure to comply may result in a data breach and compromise participant confidentiality.

7.3 Authorship and Acknowledgment

Publication authorship must align with standard journal regulations, ensuring that all authors have made a substantial contribution to the conception and design of the Sub-project, data analysis and interpretation, and drafting of the paper. In a study such as ORIGINS, there are 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 according to BMJ guidelines.

All research dissemination from the Sub-project must clearly acknowledge contributions from the Joondalup/Wanneroo community. The cohort study has been set up to attempt genuine public engagement and the ORIGINS Cohort should be recognised as active contributors, rather than just passive Participants. The following standard acknowledgement must be included in all 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 ORIGINS possible: the ORIGINS team; Joondalup Health Campus (JHC); members of ORIGINS Community Reference and Participant Reference Groups; the ORIGINS Scientific Committee; The Kids Research Institute Australia; City of Wanneroo; City of Joondalup; and Professor Fiona Stanley."

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

"ORIGINS 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 The Kids Research Institute Australia and Joondalup Health Campus." If referring to the biobank, refer to it as the ORIGINS 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

Due to ethical restrictions, ORIGINS data cannot be shared publicly. The following data sharing statement should be included in publications explaining the reasons for its unavailability:

"The data presented in this study are not publicly available. Access to ORIGINS data requires approval through its governance process, which includes endorsement from the ORIGINS Scientific Committee and Directorate, ethics approval from an NHMRC-

approved Human Research Ethics Committee, and payment of an access fee. This application process is in place due to the sensitive nature of the data, which relate to pregnancy, birth, and child health."

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

7.4 Identification

It is important that all work linked to ORIGINS is easily identified, including in electronic searches. Researchers are to include *ORIGINS 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 *ORIGINS* 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 ORIGINS. ORIGINS is a collaboration between The Kids Research Institute Australia and Joondalup Health Campus, and is one of the most comprehensive studies of pregnant women and their families in Australia to date, having recruited 10,000 families over a decade from the Joondalup and Wanneroo communities of Western Australia."

7.5 Use of the ORIGINS Logo and Assets

ORIGINS 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 Kids and Joondalup Health Campus logos, acknowledging our collaborators. It ***should not be used*** without this logo lock up, unless consultation is undertaken with ORIGINS Research and Translation Team.

Click HERE to download a JPEG of the ORIGINS tri-logo lock up for use. The logo should be used in full colour wherever possible; however it may be displayed in all black or all white if necessary. No alternative shades or colours should be used. The main brand colours of ORIGINS are Midnight Blue (#1F3B73), Azure Blue (#426EA8) and White (#FFFFFF). 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 Research and Translation Team.

7.6 Intellectual Property

JHC and The 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. Fee Schedule

C. Access to Data Form

D. Release of Biological Information Form

E. Material Transfer Agreement

F. Variation Request Form