

The ORIGINS Project Sub-Project Research Proposal

The ORIGINS Project is a community resource that invites collaborative sub-projects and initiatives.

Applicant's Name:

Date of Application:

Applicant's Institution:

Version:

Sub-Project Title:

Research Proposal for:

New Sub-Project	<input type="checkbox"/>
Grant Application	<input type="checkbox"/>

Type of Sub-Project and Resources required:

Select ALL that apply

Clinical trial/Intervention	<input type="checkbox"/>
New data collection	<input type="checkbox"/> New Questionnaires (adding to DATABANK) <input type="checkbox"/> New Measures on participants (adding to DATABANK) <input type="checkbox"/> New Sample collection (adding to BIOBANK)
DATABANK access	<input type="checkbox"/> Access to existing data
BIOBANK access	<input type="checkbox"/> Access to existing samples for laboratory analysis <input type="checkbox"/> Genetic studies
Data linkage	<input type="checkbox"/>

Research Area:

Select ALL that apply

Allergy, immunity and inflammation	<input type="checkbox"/>	Epidemiology, equity, and social justice	<input type="checkbox"/>
Fathering	<input type="checkbox"/>	Growth and development	<input type="checkbox"/>
Health economics	<input type="checkbox"/>	Mental health and wellbeing	<input type="checkbox"/>
Nutrition and metabolism	<input type="checkbox"/>	Reproduction	<input type="checkbox"/>
Environment and lifestyle	<input type="checkbox"/>	Nature relatedness	<input type="checkbox"/>
P4 Omics and systems biology	<input type="checkbox"/>	Oral health	<input type="checkbox"/>
Infections and vaccines	<input type="checkbox"/>	Brain and behaviour	<input type="checkbox"/>

COVID-19

Collaborative

ORIGINS Research Interest Group (RIG) contact:

Presented to ORIGINS RIG/s: *(Name/s, Date/s)*

Presented to ORIGINS Health Economics RIG: *(Date)*

Presented to ORIGINS Community Reference Group and/or Participant Reference Group: *(Name/s, Date/s)*

Sub-Project Team (Please indicate and highlight if team members are to be located outside Australia)

Chief Investigator:

Title and Name

Position and Institution

Qualifications

Address

Employed ORIGINS staff member

Telephone

Email

ORIGINS Chief Investigator:

Title and Name

Position and Institution

Qualifications

Telephone

Email

Co-Investigator:

Title and Name

Position and Institution

Qualifications

Telephone

Email

Co-Investigator:

Title and Name

Position and Institution

Qualifications

Telephone

Email

Co-Investigator:

Title and Name

Position and Institution

Qualifications

Telephone

Email

Sub-Project Team Members *(add more as required)*

Time Frame:

Expected start date *(day/month/year)*

Expected completion date *(day/month year)*

Ethics:

Following approval of the Research Proposal, the researchers are responsible for obtaining approval from the appropriate Human Research Ethics and Governance Committee(s) before access and use of the ORIGINS cohort, data and/or biological information may commence. Please liaise with the ORIGINS Research and Translation Team ORIGINSResearch@telethonkids.org.au in relation to all submissions to Ethics and Governance Committees. A copy of the final application(s), HREC and governance approval(s) and amendments are to be provided to the ORIGINS Research and Translation Team.

To be sought (Committee name(s))	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>
Not necessary (Provide justification)	<input type="checkbox"/>

Funding (including scholarships):

To be sought	<input type="checkbox"/>
Application to funding body submitted	<input type="checkbox"/>
Obtained	<input type="checkbox"/>
No extra funding required	<input type="checkbox"/>

Funding Body: (Name)

Submission Deadline: (Date)

Principal Applicant:

Administering Institution:

Are any commercial interests funding the sub-project? (If yes, provide details)

Funding totals: (Obtained or applied for)

Year 1	Year 2	Year 3	Year 4	Year 5	Total
\$	\$	\$	\$	\$	\$

Funding (add more as required)

ORIGINS Administration and Access Fees:

ORIGINS Administration and Access Fee discussed with ORIGINS Management: *(Name/s, Date/s)*

Quote provided: *(Details, Date)*

Feasibility discussed with ORIGINS Project Management Group:

Select ALL that apply

Program Manager	<input type="checkbox"/>	Biobank Team	<input type="checkbox"/>
Engagement Team	<input type="checkbox"/>	Research and Translation Team	<input type="checkbox"/>
Databank Team	<input type="checkbox"/>	Stakeholder Management Team	<input type="checkbox"/>

Agreements:

A Sub-Collaboration Agreement between Telethon Kids, Joondalup Hospital and external researchers (*Sub Collaboration Agreement*) has been established for the ORIGINS Project. For researchers who are internal employees of Telethon Kids or Joondalup Hospital, there is 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.

Are there any existing or anticipated funding, collaboration or other agreements that are in place for this sub-project? *(Details)*

Budget:

Please attach a budget to this research proposal that details of all estimated costs for the duration of the sub-project including ORIGINS Administration and Access fees.

Sub-Project Description

Summary: (*~ 200 words, a short lay summary of intended research*)

Background & rationale:

Research question, aims and objectives: *(indicate how these align with the goals and vision of The ORIGINS Project)*

Overview of methods: *(include the below items as a minimum)*

- *Specify study design – e.g. Double blinded RCT, cross-sectional observational*
- *Specify number of participants, and where appropriate, number of cases and controls (sample size)*
- *Specify any selection criteria (inclusionary, exclusionary)*
- *Clearly outline any new/additional measures (data and/or biological sample collections) or timepoints*
- *Specify by who/how and where any new/additional measures (data and/or biological sample collections) or assessment timepoints are to be conducted, collected, processed and/or analysed (particularly if not local)*
- *Specify by who and where any required additional recruitment/consenting tasks*
- *Specify timeframe/timeline*

Data analysis including statistical justification for sample size and power:

Detail how/what this sub-project will contribute to the ORIGINS platform:

Specify if and where any biological samples or data will be sent outside Australia

Overview of community liaison/engagement:

Outline planned research dissemination and translation: *(specify planned publications, presentations, changes to clinical practice; if it has a translational component, explain how knowledge created from this research can be used to drive advances in an area of health and development outcomes)*

Detail any expected benefit/s to ORIGINS participants and/or the Joondalup/Wanneroo community:

Detail any feedback that will be provided to participants and/or the Joondalup/Wanneroo community:

Data and/or biological samples to be used in the sub-project:

Please specify data and/or biological samples requested from the ORIGINS Databank and/or Biobank.

	Antenatal		Postnatal				Childhood			
	20 weeks	36 weeks	Birth	2 mths	4 mths	6 mths	1 yr	1.5 yrs	3 yrs	5 yrs
BIOLOGICAL COLLECTIONS										
Blood	M <input type="checkbox"/> F* <input type="checkbox"/>	M <input type="checkbox"/>					C <input type="checkbox"/> F <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
Urine	M <input type="checkbox"/>	M <input type="checkbox"/>		M <input type="checkbox"/> C <input type="checkbox"/>		M <input type="checkbox"/> C <input type="checkbox"/>	C <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
Buccal swab	M <input type="checkbox"/> F* <input type="checkbox"/>	M <input type="checkbox"/>	F <input type="checkbox"/>				M <input type="checkbox"/> C <input type="checkbox"/> F <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
Saliva	M <input type="checkbox"/> F* <input type="checkbox"/>	M <input type="checkbox"/>	F <input type="checkbox"/>				M <input type="checkbox"/> C <input type="checkbox"/> F <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
Stool	M <input type="checkbox"/>	M <input type="checkbox"/>		M <input type="checkbox"/> C <input type="checkbox"/>		M <input type="checkbox"/> C <input type="checkbox"/>	C <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
House dust		M <input type="checkbox"/>					M <input type="checkbox"/>		M <input type="checkbox"/>	M <input type="checkbox"/>
Meconium			C <input type="checkbox"/>							
Cord blood/gasses			C <input type="checkbox"/>							
Guthrie card			C <input type="checkbox"/>							
Placenta			C <input type="checkbox"/>							
Colostrum			M <input type="checkbox"/>							
Breastmilk				M <input type="checkbox"/>		M <input type="checkbox"/>	M <input type="checkbox"/>			
Hair	F* <input type="checkbox"/>	M <input type="checkbox"/>					M <input type="checkbox"/> F <input type="checkbox"/>			
CLINICAL ASSESSMENT										
PEA POD / BOD POD			C <input type="checkbox"/>						C <input type="checkbox"/>	C <input type="checkbox"/>
TEWL		F* <input type="checkbox"/> M <input type="checkbox"/>					F <input type="checkbox"/> C <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
Skin prick test							C <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
Eczema assessment							C <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
Anthropometry	F* <input type="checkbox"/> M <input type="checkbox"/>						F <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
Developmental review							C <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
Developmental assessment****							C <input type="checkbox"/>		C <input type="checkbox"/>	

	Antenatal		Postnatal				Childhood								
	20 weeks	36 weeks	Birth	2 mths	4 mths	6 mths	9 mths	1 yr	1.5 yrs	2 yrs	2.5 yrs	3 yrs	3.5 yrs	4 yrs	5 yrs
DATA - ACTIVE PARTICIPANTS															
ORIGINS (online, REDCAP)	M <input type="checkbox"/> F* <input type="checkbox"/>	M* <input type="checkbox"/>		M <input type="checkbox"/> C <input type="checkbox"/>		M <input type="checkbox"/> C <input type="checkbox"/>		M <input type="checkbox"/> C <input type="checkbox"/>	M <input type="checkbox"/> C <input type="checkbox"/>	M <input type="checkbox"/> C <input type="checkbox"/>			M <input type="checkbox"/> C <input type="checkbox"/>	M <input type="checkbox"/> C <input type="checkbox"/>	M <input type="checkbox"/> C <input type="checkbox"/>
Ages & Stages questionnaire***					C <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>		C <input type="checkbox"/>		C <input type="checkbox"/>		C <input type="checkbox"/>	C <input type="checkbox"/>
Australian Eating survey/ Child Food Frequency Questionnaire***	M <input type="checkbox"/>	M <input type="checkbox"/>				M <input type="checkbox"/>		M <input type="checkbox"/> C** <input type="checkbox"/>		C** <input type="checkbox"/>			M <input type="checkbox"/> C** <input type="checkbox"/>		M <input type="checkbox"/> C** <input type="checkbox"/>
Strengths and Difficulties Questionnaire***												C <input type="checkbox"/>			
Early Conners***												C <input type="checkbox"/>			C <input type="checkbox"/>
Copenhagen Infant Mental Health Screen								C <input type="checkbox"/>							
JHC health questionnaires (paper)	M <input type="checkbox"/> F <input type="checkbox"/>														
JHC antenatal (Genie)	M <input type="checkbox"/>	M <input type="checkbox"/>													
JHC birth & postnatal (Meditech)			M <input type="checkbox"/> C <input type="checkbox"/>												
JHC Special Care Nursery (database)			C <input type="checkbox"/>												
Government data (linked data) (MBS, PBS, AEDC, Education etc)															
DATA - NON-ACTIVE PARTICIPANTS															
JHC health questionnaires (paper)	M <input type="checkbox"/> F <input type="checkbox"/>														
JHC antenatal (Genie)	M <input type="checkbox"/>	M <input type="checkbox"/>													
JHC birth & postnatal (Meditech)			M <input type="checkbox"/> C <input type="checkbox"/>												
JHC Special Care Nursery (database)			C <input type="checkbox"/>												

M = Mother | F = Father/Partner | C = Child/Infant | *Father/partner completes once antenatally **Child Food Frequency Questionnaire ***Standardised questionnaires **** For 10 to 15% of Active Participants | MBS = Medicare Benefits Scheme | PBS = Pharmaceutical Benefits Scheme | AEDC = Australian Early Development Census

With all data requests, a Data Sharing Agreement and Data Management Plan will need to be completed in collaboration with the ORIGINS Databank Team in order to specify the exact variables you require for use and analysis.

With all biological sample requests, a Release of Biological Information and Material Transfer form will need to be completed in collaboration with the ORIGINS Biobank Team in order to specify the volume/s you require for analysis.

Include details of any specific variables requested from questionnaire data:

Additional data and/or biological samples to be collected in the sub-project:

*If your proposed sub-project includes **new data collection**, then we require sufficient detail to assess the feasibility and appropriateness of the additions to the ORIGINS Project and the extent to which clinician and participant burden will be increased. Please complete the following table and append to this Research Proposal any relevant Standard Operating Procedures (SOPs). Please note that you are obliged to harmonise sampling and outcome measures where possible and appropriate.*

	New Questionnaire/s	New Biological Sample/s	New Measure/s
Item			
Description (variables, data, samples, measures)			
Participant (mother, father, child)			
Number (sample size)			
Time point/s (specific antenatal, postnatal or childhood timepoints)			
Time involved in collection			
Staff involved in collection			
Space involved in collection			
SOPs (processing, sample analysis)			
Consumables required			
Cost of collection			
Storage of collection			

Signed for and on behalf of all investigators listed above who have read and agree to the contents of this form

Chief Investigator: *(print name)*

Date signed:

Signature:

Please email to ORIGINS Research and Translation Team ORIGINSResearch@telethonkids.org.au

Additional Documents: *(as required)*

CVs of Project Team Members	<input type="checkbox"/>
Sub-Project specific Participant Information Sheet (or equivalent)	<input type="checkbox"/>
Sub-Project specific Consent form/s	<input type="checkbox"/>
Sub-Project specific Withdrawal form	<input type="checkbox"/>
Sub-Project and/or recruitment protocol/s	<input type="checkbox"/>
Sub-Project specific Questionnaire/s	<input type="checkbox"/>
Sub-Project specific Standard Operating Procedure/s (SOP/s)	<input type="checkbox"/>
Any existing sub-project specific agreements, contracts, policies and/or plans	<input type="checkbox"/>

Details:

References: