

Data access protocol

Procedures for collaborative work based on the New Zealand Pregnancy Cohort and Baby Cohort

If a researcher(s) external to the New Zealand Pregnancy Cohort (NZPC) and Baby Cohort Core Investigators and the wider Pharmacoepidemiology Research Network Core Academic Group approaches us (the NZPC and Baby Cohort Core Investigators) about undertaking collaborative work based on the NZPC and Baby Cohort:

1. We will ask the researcher(s) to provide a brief 1 – 2 page outline of their research question and proposed investigation, and to identify potential sources of funding for the project (to cover the costs of data management time, open access publication fees etc).
2. If the researcher(s) is unknown to us, we will ask them to provide a copy of their CV.
3. At least one of us will meet with the external researcher(s) to discuss the proposed project, including an assessment of its scientific validity, scope, and feasibility.
4. We will also ask the researcher(s) to disclose any potential conflicts of interest. It is important that our research should be, and should be seen to be, impartial. Therefore we will not:
 - (i) Accept funding for research from pharmaceutical companies – be it direct or indirect funding (e.g. money from honoraria or residual funds from earlier industry-funded projects); or
 - (ii) Undertake research with employees of pharmaceutical companies; or
 - (iii) Undertake research with investigators who have current or recent conflicts of interest that might reflect adversely on the perceived independence of the research
5. If the proposed project is considered scientifically sound and feasible, and there are no conflicts of interest, it will be discussed with other members of our group (the NZPC and Baby Cohort Core Investigators) and will be prioritised in relation to other work.
6. A memorandum of understanding between our group and the external researcher(s) will be drawn up which will cover matters such as who will be responsible for designing the study, obtaining funding, writing the protocol, obtaining ethical approval, writing the data management and analysis plans, undertaking the statistical analyses, interpreting the results, drafting and submitting manuscripts to peer-reviewed journals, and other dissemination activities.
7. We will then work with the external researcher(s) to develop a full protocol; obtain ethical approval; manage and analyse the data; interpret the results; draft and submit manuscripts; and undertake other dissemination activities.

8. External researchers will never be given access to an analysis dataset for a project unless at least one of the Co-ordinating Investigators is involved as a co-investigator.
9. If the external researcher(s) is to be given access to an analysis dataset they will be required to:
 - (i) Apply for a University of Otago username to register on the University network, connect to the project-specific analysis dataset via a virtual machine with restricted access permissions, and work solely within the University of Otago secure environment.
 - (ii) Sign a Data Release Agreement (see next page).

Data Release Agreement for External Researchers

Title of project:

I confirm that I will:

1. Take all reasonable steps to prevent unauthorised, either deliberate or unintentional, access to the data for the project. The data will be provided on a University of Otago virtual machine, for which I will require a University of Otago username and password, and I will not share the username or password or make any attempts to copy the data. Nor will I attempt to identify individuals from the data.
2. Use standardised New Zealand Pregnancy Cohort (NZPC) and Baby Cohort definitions and variables where applicable in analysis and reporting. I will not distribute NZPC and Baby Cohort technical documentation or data dictionaries without prior approval of Dr Sarah Donald and Associate Professor Lianne Parkin.
3. Provide reports to Dr Donald and A/P Parkin on progress in analyses when requested.
4. Submit a draft of all forms of dissemination about this project, including media releases, verbal, or written presentations, to Dr Donald and A/P Parkin for approval prior to release/submission/presentation. Programming code may also be requested.
5. Acknowledge the source of the data and the role of the NZPC and Baby Cohort Core Investigators, funders, and/or sponsors in any dissemination.
6. Accept that access to the data will cease once the objectives of the project have been met or as otherwise decided by Dr Donald and A/P Parkin.

Name:

Signed:

Date:

Research Student Confidentiality Agreement

Title of project:

1. I understand that at all times I must maintain confidentiality of all information I have access to during the course of my study.
2. I will not attempt to identify individuals from the data.
3. I understand that the unit-record project data must only be used on an approved on-site computer at the University of Otago, and no unit-record project data should be held on a personal computer, memory stick, or accessed remotely from any other computer.
4. I will not disclose any information related to individuals at any time to anyone outside the project research group.*
5. I will not disclose any results of the research outside the project research group prior to publication without consent of the group
6. I will not discuss the detailed topics and methods of the research outside the project research group without prior permission.

* The 'project research group' will include at least one of the Co-ordinating Investigators and may also include other researchers.

Name:

Signed:

Date: