

ABCD Collaboration Policy

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This document describes the organization of the ABCD (Amsterdam Born Children and their Development) study, the opportunities for collaboration and the procedures for the use of research data. It also serves as an appendix to collaboration related contracts with ABCD.

1. General

1. ABCD has been set up to study the association between maternal lifestyle, medical, psychosocial and environmental conditions during pregnancy and children’s health at birth as well as in later life. ABCD is being carried out by the Amsterdam UMC. Various departments of the Amsterdam UMC and other institutions are participating in the various phases of the study. The ABCD team is open to proposals for collaboration with internal and external research teams.
2. Proposals regarding scientific collaboration should be submitted to the principal investigator (PI). The proposals will then be considered by the PI with advice from the ABCD team, on the basis of: 1. compatibility with the general objectives of the ABCD study, 2. the quality of the research proposal, 3. possible overlap with other studies, 4. the use of biological material, 5. logistical feasibility and 6. the (financial) contribution to be made. See appendix 1 for details on the types of research question ABCD can be used for. See appendix 2 for a summary of the study design and an overview of the ABCD data collection.



3. Scientific collaboration is possible only after approval of the proposal by the PI, with advice from the ABCD team, and subject to agreement that the matters referred to in this document will be fulfilled.
4. Researchers working with ABCD data should comply to the principles of conduct for research integrity in and across Amsterdam UMC.

2. Organization

1. The ABCD team consists of the PI, Project Coordinator, (PhD-)researchers, data manager, data steward, and research assistants.
2. The PI has ultimate responsibility for ABCD. The PI is responsible for progress and the day-to-day operations, acquisitions not covered by the normal scientific subsidy applications, the assessment of research plans and formulation of the budget. The PI, the Financial Controller of AMC Medical Research bv. (AMR) and the Legal Advisor together undertake the financial and legal management.
3. The Project Coordinator is responsible for the day-to-day data collection, archiving and data transfer activities.

3. Researchers

1. Researchers affiliated with a Dutch or international research institute may request data or samples to conduct a study that fits within the general aims of ABCD.
2. PhD students
 - a. Scientific participation in ABCD often involves the appointment of a PhD student whose doctoral research is based at least partly on the ABCD study data.
 - b. A PhD student whose doctoral research is based exclusively on the ABCD study data contributes to the general ABCD activities (i.e. data collection, supervising internship and cleaning data) for one full-time year. The year's work may be spread out over the first two or three years of the appointment. The ABCD activities undertaken are not necessarily related to the student's own research. We aim for a situation where, during a period of contribution to general ABCD activities, half of the student's time can be devoted to his/her own research. However, priority is given to the general ABCD activities.
 - c. PhD students are required to sign a ABCD contract, which will be provided by the Project Coordinator.
 - d. If the PhD student's doctoral research is based only partly on ABCD data, the amount of time contributed to general ABCD activities is adjusted on a pro rata basis.
 - e. If a disagreement arises regarding the contribution that a PhD student should make to general ABCD activities, the final decision lies with the PI .
 - f. The general ABCD activities undertaken by a PhD student are supervised by the PI and the Project Coordinator. Scientific supervision of the PhD student's activities in connection with his/her own research project is provided by his/her thesis supervisor(s).
 - g. PhD students working within ABCD participate in the general meetings and activities for ABCD staff and researchers.
3. Students
 - a. Students (supervised by researchers affiliated with the Amsterdam UMC or Amsterdam Public Health research institute (APH)) may also request data to conduct



- a study that fits within the general aims of ABCD. Preferably these are Master's students.
- b. Students contribute to general ABCD activities (i.e. data collection or cleaning) at least 20% of their time of their internship, with a minimum of three weeks.
 - c. Students are required to sign an ABCD contract, which will be provided by the Project Coordinator. If a disagreement arises regarding the contribution that a student should make to general ABCD activities, the final decision lies with the PI .
 - d. The general ABCD activities undertaken by a student are supervised by the PI and the Project Coordinator. Scientific supervision of the student's activities in connection with his/her own research project is provided by his/her thesis supervisor(s).
 - e. Students working within ABCD participate in the general meetings and activities for ABCD staff and researchers.
4. In consultation with the PI, alternative means of scientific collaboration may be agreed.

4. Procedures for the use of data

1. An order to secure approval for a research project within ABCD or with ABCD data, a publication proposal must be submitted:
Publication proposals should be submitted using the ABCD Publication Proposal Form (appendix 3). The PI assesses research proposals on the basis of the following criteria: compatibility with the general objectives of the ABCD study, the quality of the research proposal, possible overlap with other ongoing studies, the use of biological material, the logistical feasibility and the (financial) contribution to be made.
2. In order to specify the exact data to be used for a proposal, a data request is submitted:
A data request should accompany a publication proposal. Data requests are submitted using the ABCD Data Request Form (appendix 4). Information regarding the available data can be found in the ABCD codebook, which can be requested from the PI or the Project Coordinator. On the basis of the data request, a data file is created after the approval of the proposal, Data Transfer Agreement (DTA) is signed and the preregistration of the research proposal on Open Science Framework (OSF), which is then used for the analyses associated with the relevant publication or study.
3. Publication proposals, date of registration on OSF and data requests should be submitted to the ABCD Project Coordinator (n.vanlieshout@amsterdamumc.nl), using the appropriate forms.
4. No data can be exchanged with other researchers or institutes other than defined in the related contracts(s) (DTA).
5. No data can be stored on locations different than those defined in the related contract(s) (DTA).
6. When the research project is finished, all data must be returned to ABCD following the DTA defined in the related contracts. ABCD will archive all data-files. All copies of the data still in the possession of the investigators should be destroyed and confirmation of this must be communicated to ABCD.

5. Collaboration in data collection

1. The PI has the final say over all decisions to share data.
2. All data will be stored centrally at the department of Public and Occupational Health of the Amsterdam UMC (G disc).



3. If sub-studies are being performed, other departments or researchers within the Amsterdam UMC may be responsible for the content and execution of part of the data collection.
4. In cases where information about participants' names, addresses, places of residence and phone numbers is required for additional data collection (sub-studies), the researcher first must sign a confidentiality agreement provided by ABCD. After this, the researchers will gain access to the folder within Amsterdam UMC secure environment containing that information. When the project concludes, the access to the folder will be revoked.
5. Information about participants' names, addresses and places of residence must be stored in a safe place and strictly separated from research data. ABCD must be informed as to which participants have been contacted regarding participation in a sub-study and whether each of them agreed to participate.
6. Sub-study data or samples may in exceptional cases be stored and processed by sub-study researchers, but always within the Amsterdam UMC environment. At least two researchers should have access to these data, and a back-up will be stored in the central ABCD database. Additional conditions may be agreed between ABCD (PI and Project Coordinator) and the researcher(s).
7. In case sub-study data are stored and processed by sub-study researchers (but within the Amsterdam UMC), data will be requested via the ABCD procedures, and the ABCD PI still has the final say over all decisions to share the data.
8. Data for scientific analyses never contains traceable data such as the participants' names, addresses and places of residence or other additional data that is traceable to the participant.
9. Sub-study researchers are responsible for compliance to all agreements that are made with ABCD.

6. Financial arrangements

1. The costs associated with a PhD student's participation in ABCD are borne by the department that initiates the relevant project. The associated costs include both the personnel costs (PhD student, personnel for data collection) and materials costs not already covered by ABCD or another department.
2. For each PhD project, ABCD will additionally receive: €25,000 as a contribution to the general data collection infrastructure (if the PhD student does not contribute to the data collection or general ABCD activities in the manner described in section 3).
3. The above contributions are treated as financial contributions to the cost of the infrastructure that is required for general data collection within ABCD.
4. The contributions payable in respect of non-doctoral research undertaken on a part-time basis and doctoral research undertaken only partly within ABCD are adjusted on a pro rata basis, subject to a minimum of €10,000 per research question or publication. The exact amount is determined by the PI on a case-by-case basis. It is also possible to contribute in kind to the data collection costs by providing equipment or personnel capacity of an equivalent value. For example, consideration would be given to a proposal to contribute to the data collection through an internship involving one or two days per week for the duration of the internship.
5. The contributions specified above are payable in respect of projects that utilize previously collected data. If additional data need to be collected or if use is made of stored biological material, additional costs may be payable.



7. Publication rules

1. A possible co-author must be given sufficient time to make a substantial contribution (two weeks to read draft results or a draft article). The person in question must then actually make a substantial contribution in order to justify being credited as a co-author. International guidelines for co-authorship (ICMJE) will apply. [ICMJE | Recommendations | Defining the Role of Authors and Contributors](#)
2. At least two researchers affiliated with ABCD must co-author every ABCD publication.
3. In principle, every ABCD publication should be co-authored by a representative of the Amsterdam UMC, department of Public and Occupational Health.
4. If possible, the title of any publication (including abstract submissions) should include 'the ABCD study'.
5. Every publication must at least include the standard ABCD acknowledgement (Appendix 5). Variations of this can be discussed with the PI.
6. Upon publication, ABCD will receive the complete dataset (including derived variables) and syntaxes which document how the results of the publication were obtained. These will be archived by ABCD for audit purposes.
7. In principle, the authorship guidelines set out above apply equally to ABCD sub-studies. In the case of a sub-study in which ABCD-participant data were used only for participant selection (without ABCD cohort data being used), in principle only one ABCD member needs to act as a co-author.
8. The authorship guidelines set out above apply equally to publications whose principal author is not employed by the Amsterdam UMC.
9. The authorship guidelines set out above apply equally to preprint publications, internships, posters and presentations, since such items normally constitute (draft) publications.
10. In the event of uncertainty or disagreement regarding authorships of ABCD members, the PI has the final say. Regarding the authorships of other co-authors, the applicant of the publication proposal has the final say.

8. ABCD contact list

ABCD general mail:

Abcd-studie@amsterdamumc.nl

Principal investigator:

Dr. Tanja Vrijkotte

t.vrijkotte@amsterdamumc.nl

Project Coordinator:

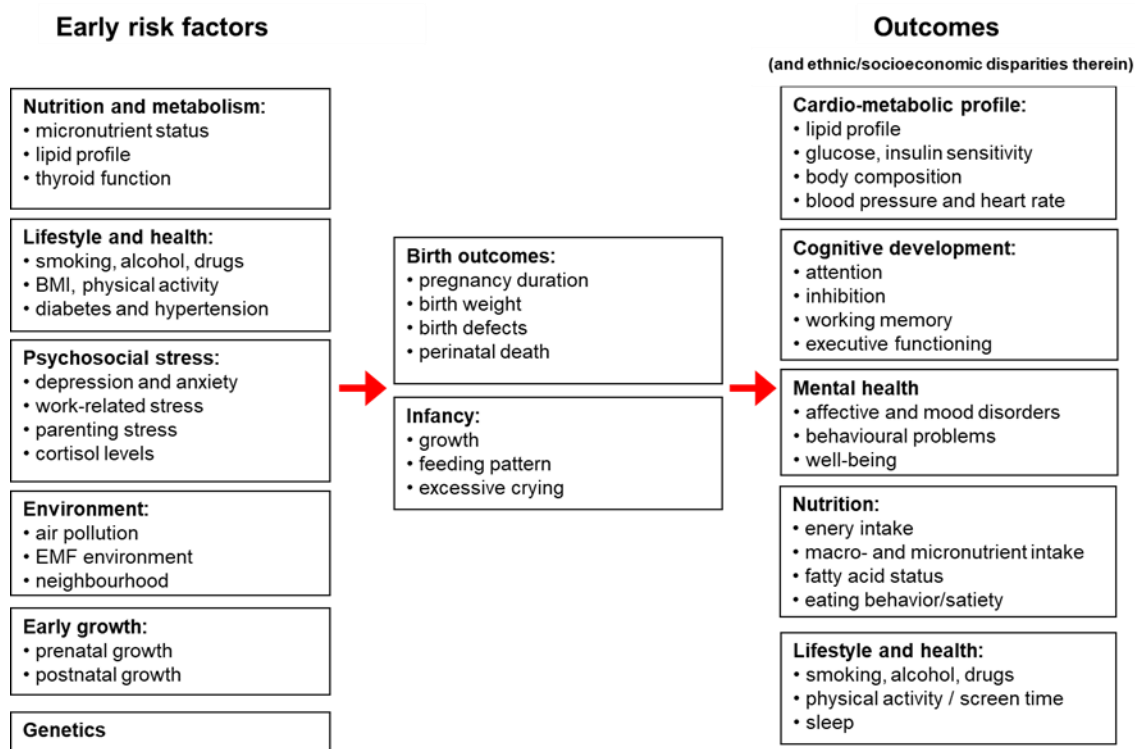
Noekie van Lieshout

n.vanlieshout@amsterdamumc.nl



9. Appendices

Appendix 1. Scope of research questions



Appendix 2. Study design

The ABCD-study is a multi-ethnic prospective birth cohort study. Figure 3 shows that our study started between January 2003 and March 2004, all pregnant women living in Amsterdam were invited to participate during their first prenatal visit to an obstetric care provider. During this period 12 373 women were sent a questionnaire covering socio-demographic characteristics, obstetric history, lifestyle and psychosocial conditions. 8266 women returned the questionnaire, a response rate of 67%. This questionnaire included an informed consent form in which the women could grant permission for follow-up (n=7050; 85%) as well as consenting to review of their medical charts (n=7043; 85%). In addition, women were asked to participate in the ABCD-biomarker study (n=4389; 53%). In phase 2, when the children were 3 months old, 6854 women were sent the infant questionnaire. 5218 mothers (5131 mothers of singletons and 87 mothers of multiples) filled out the questionnaire. After these questionnaires were completed, it was decided to complete follow-up measurements on singleton infants only. Of the 6735 women who gave birth to live-born singleton infants, 6575 women gave permission to collect growth data. Growth data was obtained from the Youth Health Care service, where, until the children were 4 years old, specially trained nurses conducted an average of 14 standardized routine measurements to monitor growth and feeding patterns. The information for 5865 children was available for collection and was digitalized into the ABCD-database. Phase 3 started when the children turned 5 years old. The addresses of 6161 mother were retrieved from the Youth Health Care registry and these mothers were sent a questionnaire which was returned by 4488 mothers. 3321 children participated in the health check between 2008-2010 and in a subsample of 2003 children, fasting blood samples were drawn via finger prick.⁽³¹⁾ Phase 3b started when the children were 7-8 years old, a new questionnaire focusing on electromagnetic fields (EMF), allergy and sleep was completed by 3460 parents. For



phase 4, at age 11-12 years, we have been able to extract the addresses of 5682 children from the registry of the Municipal Health Services in order to make contact with the ABCD participants for the follow-up measurements. A total of 3027 children, 3031 mothers, and 2270 fathers filled in the questionnaire. 1082 children participated in the physical measurements, which included anthropometric, cardiovascular, and physical activity measurements. In phase 5, 5291 children and their mother and father were sent a questionnaire. A total of 2291 children, 2189 mothers, and 1418 fathers filled in the questionnaire. Additionally, monitor data from the participants' telephones, such as screen time and steps a day, were collected (n=732). Phase 6 only entailed questionnaires, which were sent to 5448 children and their mother and father. 1678 children, 1324 mothers, and 951 fathers completed the baseline questionnaire. They also received five smaller follow-up questionnaires. 1156 children, 975 mothers, and 606 fathers completed all follow-up questionnaires. However, the data cleaning is still in progress, therefore these numbers are not definitive.

Appendix 3. Publication proposal form

ABCD Publication Proposal Form

This form should be used to submit a proposal regarding the use of ABCD data for a publication

Up to two A4 pages (excluding tables, where relevant)

Manuscript #	Date of submission	Date of approval
1. Applicant		
2. Title / subject of the publication		
3. Proposed authors	<i>Who is the proposed principal author?</i> <i>Who are the proposed co-authors?</i>	
4. Principal author's contact details		
5. Background		
6. Research question	-	
7. Data and population	<i>What inclusion and exclusion criteria are to be applied (e.g. age, ethnicity, etc.)?</i>	
8. Analysis plan	<i>Describe on a step-by-step basis the statistical analyses to be performed (type of regression, tests, etc.) in order to answer the research question (using what dependent and independent variables, what confounders, etc.). What tables will be produced? (Please provide unpopulated tables if possible.)</i>	
9. Timing	<i>When will the data analysis start?</i> <i>When will the manuscript be written?</i> <i>When is the manuscript likely to be completed?</i>	

Appendix 4. ABCD Data Request Form

Data request		
Name dataset	Variable name	Description
<i>For example: 2-vragenlijst-zwangerschap</i>	<i>QZW2</i>	<i>age of pregnant woman</i>
	<i>QZW7A</i>	<i>Years education after elementary school</i>
	<i>etniciteit</i>	<i>physiological ethnicity per grandmonther's birth country</i>
	<i>parit</i>	<i>number of earlier labours</i>
	<i>gravid</i>	<i>number of pregnancy (including current)</i>
	<i>alcBn</i>	<i>glasses of alcohol during pregnancy</i>

Appendix 5. Standard acknowledgement

Every publication which is based on ABCD data should include the following acknowledgement (variations of this can be discussed with the PI):

"The authors would like to acknowledge the ABCD study participants for their contribution and the ABCD team for data collection and management."