# **ANALYSIS PLAN PROPOSAL**

# **TO THE PSYCHGEN EXECUTIVE COMMITTEE**

|  |  |  |  |
| --- | --- | --- | --- |
| **Brief summary – to be filled out by the PsychGen administrators** | | | |
| ID number: | | | |
| Person(s) with data access: | | | |
| Collaboration agreement and project: | | | |
| Data Sources (tic the boxes that apply) | | | |
| Tags for *topic:* | | | |
| Tags for *methods:* | | | |
| HPC: | | | |
| Costs: | | | |
| Relevant PsychGen/PaGE grants: | | | |
| MoBa | NPR | KUHR | SSB |
| NAV | ABC | MFR |  |

Document versioning

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Version number: | Date: | Description of change: | Author: | Approval date: | Approved by: |
| 1.0 |  |  |  |  |  |

**Information for** **the** **proposer**

To propose a publication based on data in the PsychGen project (PDB2306, TSD p-471), please fill out the form below. The PsychGen executive committee (PsychGen EC) will review the proposal. The PsychGen EC (PI Alexandra Havdahl, co-PI Helga Ask, Laurie Hannigan and project coordinators) will assess if the proposal is covered by ethical approvals, Data Protection Impact Assessment and the PsychGen agreement with MoBa and other data sources, and consider potential overlap with other approved paper proposals in PsychGen. **NB: other projects have access to the same data sources that are available in PsychGen, and we are not able to provide any assurances whatsoever as to whether the proposal overlaps with ongoing work elsewhere.**

If the analysis proposal is approved, one of the researchers in the PsychGen EC will be appointed as the main contact person, and will be responsible for the steps in the process outlined below. The time to get access to data will depend on whether the proposed research questions and data are covered by existing approvals or not.

For researchers not employed at the Norwegian Institute of Public Health (NIPH), approved analysis plan proposals will be attached to the collaboration and data processing agreement between NIPH and the institution where the researcher is employed.

# Analysis plan

|  |  |
| --- | --- |
| **Contact person** |  |
| **Position** | Klikk her for å skrive inn tekst. |
| **Institution** | Klikk her for å skrive inn tekst. |
| **Date of proposal** |  |
| **Working title for the manuscript** | |
|  | |
| **Background**  (approx. 100 words) | |
|  | |
| **Primary and secondary aims & research questions**  (approx. 100 words) | |
|  | |
| **Methods** (sample selection, key measures, and analytic approaches)  NB. Just mention key measures here, and include an exhaustive variable list on the next page. | |
|  | |
| **User engagement (Public and patient engagement/stakeholder involvement)**  Brief description of user engagement in project/article (max 100 words) | |
|  | |
| **Pre-registering and open access** Brief description on plans for preregistering and how you will secure open access | |
|  | |
| **Contact person at PsychGen** |  |
| **Principal Investigator at collaborating institution**  **(if applicable)** |  |
| **Funding for the work (list costs and how they will be covered)** |  |
| **Name(s) of people who need data access** |  |
| **Who will contribute as first author(s)?**  ***If joint first authorship, e.g., between an external and PsychGen analyst, specify contributions with reference to CRediT roles <https://credit.niso.org/>***  *Note that changes in relative contributions should be submitted for approval as an amendment to the analysis plan* | Klikk her for å skrive inn tekst. |
| **Who will contribute as last author(s)?**  ***If joint last authorship, e.g., between an external and PsychGen PI, specify contributions with reference to CRediT roles <https://credit.niso.org/>***  *Note that changes in relative contributions should be submitted for approval as an amendment to the analysis plan* | Klikk her for å skrive inn tekst. |
| **Tentative list of other co-authors (list names)**  ***Specify expected contributions with reference to CRediT roles <https://credit.niso.org/>*** | Klikk her for å skrive inn tekst. |
| **Potential journals** | Suggested journal |
| **Tentative timeline for the work** |  |
| **Estimated submission date** |  |

## Full variable list:

Only include variables that are directly relevant and necessary to address your aims and research questions (consider data minimization, and justify your choices in the bottom row).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **MoBa genomic data**  (e.g., offspring genotype data) | **Medical birth registry**  (e.g., offspring birth-weight) | **Moba questionnaire variables**  (e.g., offspring anxiety measures age 3) | **ICD-10 codes from NPR**  (e.g., offspring anxiety) | **ICPC-2 codes from KUHR**  (e.g., offspring anxiety) | **SSB variables**  (socio-economic measures) e.g., maternal education level) |
| **Exposures** |  |  |  |  |  |  |
| **Outcomes** |  |  |  |  |  |  |
| **Covariates** |  |  |  |  |  |  |
| Briefly justify the direct **relevance and necessity** of these variables to address the aims/research questions | **Relevance:** | **Relevance:** | **Relevance:** | **Relevance:** | **Relevance:** | **Relevance:** |

## Computational needs

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| **Do you need High Performance Computing (HPC) recourses?** If your analysis is computationally demanding then you can discuss the potential use of HPC with us. |  |

## Costs

If there are costs with this analysis plan, the PsychGen PI will add details here before the plan is finalised.

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| --- | --- |
| **We have agreed on the following costs (e.g., HPC, data expenses) for the current article.** Applicable only if these costs are covered by the collaboration agreement. |  |

## Definitions and acronyms in this document:

**REC approval:** Regional Committees for Medical and Health Research Ethics. An approval of the proposed research by REC is mandatory. Norwegian Principal Investigators (PI) are eligible to apply.

**PI:** Principal Investigator.

**DPIA:** Data Protection Impact Assessment.

**TSD:** Services for Sensitive Data. A platform to collect, store, analyse and share sensitive data in compliance with the Norwegian regulation regarding individuals’ privacy. International researchers are eligible users.

**NIPH**: Norwegian Institute of Public Health

**Personal Data:** Any information and assessments that may be linked to an individual directly or indirectly.

#### Data sources

MoBa study: The Mother, Father, and Child cohort

ABC-study: Autism Birth Cohort Study

NPR: National Patient Registy

KUHR: Norwegian Control and Payment of Health Reimbursements Database

SSB: Statistics Norway

## Important information regarding incurring costs:

If your project requires updated data (I.e. data from a later date than what the project current has access too) or variables or data sources that the project does not yet have access to, there will be incurring costs that needs to be covered by your project.

## Important information regarding data usage:

Data in PsychGen are stored on TSD. All data analyses must be carried out within TSD. **You can only use variables and analyses as specified in approved analysis plan proposals. In case of change, an amendment application must be sent to PsychGen EC and approved before any other variables or analyses are used.**

After approval of analysis plan proposal and access to PsychGen’s TSD space, **follow PsychGen procedures for setting up an analytic project in TSD** (specified in the project Wiki and Teams group - ask for access to these resources).

**Annotate your syntax files well** so they are understandable to collaborators and MoBa Admin. The policy set by the Norwegian Mother, Father, and Child study (MoBa). All data files related to the project including results, output and syntax/scripts will be accessible for the PsychGen EC and employees at NIPH with administrative tasks in TSD.

### How to request export of data

**No Personal Data can ever be exported from TSD (screenshots are also not permitted).** Non-sensitive files which do not include any Personal Data, such as aggregated summary statistics or analytic code, can only be exported by the PsychGen PI and project coordinator. Researchers do not have access to export anything from TSD.

**If researchers wish to use non-sensitive summary results or analytic code outside of TSD (e.g., to include in a manuscript), they need to send an application** by email to the PsychGen PI and project coordinator. Follow the instructions on the Teams channel for how to request the export of summary results.

## Important information regarding publication

Please note: these are the current publication guidelines for PsychGen. At the time of article submission, you must follow the most up to date guidelines found in the PsychGen Teams channel and SharePoint page. Please reach out to the project administrator for access to these recourses.

**Ensure you follow MoBa publication guidelines** as provided on the official MoBa cohort webpage.

If your approved analysis plan proposal includes data from other sources than MoBa (national registries), ensure that you follow their respective **requirements for describing the data source and acknowledgments**.

**The use of TSD, Colossus, and data sources must be acknowledged** in your publication. You will find the approved wording for the acknowledgement in the PsychGen Teams channel.

You must follow the manuscript approval guidelines on Teams. **Please send the manuscript (along with the location of the scripts in TSD and the approved analysis plan proposal) to PsychGen EC four weeks before you aim to preprint or submit to a journal**. **Upon publication**: The first author is responsible for alerting the EC when the paper is published so they can send it to MoBa and the NIPH library for registration in the Norwegian Current Research Information System in Norway (Cristin) for reporting purposes.

## When you have completed the project

### Data cleanup on TSD

When the project is completed you are expected to delete any spesific data you have stored in your area or folder on TSD. You are free to keep a copy of your syntax and other files you might need at a later point. You should also export all files necessery for publication.

### Dissemination of results

Aim your summary at the general public, avoiding technical jargon. Also, ensure your language is accessible and respectful, avoiding terms that might discriminate against individuals with disabilities.

## Signatures (needed from all PIs and any researchers who will access the data on TSD for this proposal)

**By signing this document, you agree to not export any personal data out of TSD and only use the specified variables for the analyses agreed upon in this document. If there are any changes in outline, purpose of analyses, or key variables an amendment to this agreement will be needed.**

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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(Name) (Name)

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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(Name) (Name)

Approved by EC on date: Signature for EC representative