



## **ENIGMA Sleep Working Group** **“Analysis Plan Form”**

### **Enhancing Neuro Imaging Genetics through Meta-Analysis Consortium (ENIGMA)** **Analysis Plan Form - Sleep Working Group**

Please complete all fields and return the analysis plan form by e-mail to:

**Email:** [sleep@sbu.ac.ir](mailto:sleep@sbu.ac.ir)

[Prof. Mojtaba Zarei](#) and [Dr. Masoud Tahmasian](#), hereinafter referred to as “the ENIGMA Sleep working group chairs”

This document outlines the policy for sharing data from the ENIGMA Sleep consortium as well as policies for publication and publication credits for those who use ENIGMA Sleep data. The intent of these policies is to facilitate the sharing of data, to encourage academic productivity, and to provide a mechanism for tracking and archiving data requests, intended analyses, and publications related to and resulting from ENIGMA Sleep data.

Members of the ENIGMA Sleep consortium can submit analysis plans. Members of the ENIGMA Consortium include investigators from different centers around the world who are actively engaged in neuroimaging research and who have contributed results from primary analyses of imaging, genetic data, and/or algorithm development for the purpose of meta-analysis and/or mega-analysis, replication, and/or algorithm testing in a collaborative manner. Researchers who are not part of the ENIGMA consortium can, after consultation with the ENIGMA Sleep working group chairs and members, submit a proposal for data-analysis and publication. The ENIGMA Sleep working group chairs will always be a member of this research group and will be, together with all ENIGMA Sleep members contributing to the project, co-authors of the publications. Members will always be given the option to opt out of being an author on any publication.

This document outlines the policy for sharing data from the ENIGMA Sleep data resource as well as policies for publication and publication credits.

### **General Policy**

Each proposal for a publication with ENIGMA Sleep data will be submitted to the ENIGMA Sleep working group chairs (Mojtaba Zarei & Masoud Tahmasian) using the analysis plan form that can be found in appendix A. All consortium members are encouraged to submit such proposals, which typically involve novel analyses, answering new questions, and may involve subsets of the available sites. The ENIGMA Sleep working group chairs will screen the proposals for scientific interest, quality, overlap with other plans, appropriateness and feasibility of the proposed timeline, and whether the proposed resources committed to the project are sufficient.

Analysis plans should include a proposal for publication of a specific scientific paper, not for multiple papers on a more general topic or for a "line of work". This implies that the analysis plan should include specific research questions and hypotheses and a detailed plan for data analysis to answer those specific research questions. To attempt to avoid overlap between papers resulting from different analysis plans, the data analyses and results reported in the manuscript are limited to those described in the analysis plan. For additional analyses not described in the analysis plan a new analysis plan needs to be submitted, also if this concerns a similar topic but different data or different analyses on the same data.



## ENIGMA Sleep Working Group “Analysis Plan Form”

When the analysis plan is approved by the ENIGMA Sleep working group chairs, the proposal will be circulated amongst ENIGMA Sleep members. ENIGMA Sleep members will have 14 days from the time of the posting to opt-out of the analysis, ask for clarification, voice concerns or objections and/or give feedback to the proposal. Each analysis plan will be discussed during a conference call before the project can be initiated and the project leader can invite sites to participate. No site data will be shared without the consent of the PI of that site, who may opt to impose specific conditions or limitations on the use of the data; also ENIGMA PIs and members are not required to take part in any proposed project, they can opt out. The ENIGMA Sleep working group chairs will help enlist members who might be interested in collaborating and will assist in general coordinating tasks. Proposals will be discussed on ENIGMA-Sleep working group calls and emails to encourage the broadest participation.

Submission of a proposal implies actual plans for a publication, which will be worked on within a reasonable time frame specified in the proposal. When within 6 months after submitting a proposal there are no provable activities in that direction, the subject can be released for other interested parties.

### Publication Policy

Specific publication policies for:

#### Manuscript:

1. We request that the manuscript will be submitted to the ENIGMA Sleep working group chairs prior to circulating it to all co-authors and prior to submitting to a journal. This review is intended to ensure that provisions described in the analysis plan are correctly implemented and to avoid overlap with other ENIGMA Sleep proposals/manuscripts. The ENIGMA Sleep working group chairs will maintain confidentiality of the manuscript and will complete its review within 2 weeks.
2. People involved in the primary design, analysis and writing parts of the project will be listed as first (or joint first - denoted with an asterisk) and senior (last or joint last) authors. In addition, the ENIGMA Sleep working group chairs and all members of the ENIGMA Sleep consortium who contribute data for this project and edit the manuscript will be listed as co-authors.
3. We request that the phrase "for the ENIGMA Sleep working group" will be included on the author line of the manuscript, after the named authors. The ENIGMA Sleep website, i.e. <http://enigma.usc.edu/ongoing/enigma-sleep-working-group/>, can be used as the affiliation.
4. Funding by NIH will be acknowledged in the support acknowledgement section of the manuscript using language similar to the following:  
  
The ENIGMA-Sleep working group gratefully acknowledges support from the NIH Big Data to Knowledge (BD2K) award (U54 EB020403 to Paul Thompson).
5. All authors get to inspect the article before it is submitted to a journal.
6. Active approval of all authors on the article's content and their co-authorship is required before it is submitted to a journal.
6. It is the responsibility of the first author that the guidelines according authorship are followed, that the sample and the research-methodology are described correctly and that references to former relevant ENIGMA Sleep publications where appropriate are made.



## **ENIGMA Sleep Working Group “Analysis Plan Form”**

### **Conference poster and talk abstracts:**

1. If the conference allows listing all contributing authors, please include all contributing authors on the author line. For most conferences additional names may need to be submitted to the conference separately.
2. If the conference has a hard limit on contributing authors (many do), include the project chairs / major contributors, and as co-authors the ENIGMA Sleep working group chair, co-chair, overall ENIGMA PI, and the statement "on behalf of the ENIGMA Sleep Working Group". For the ENIGMA Sleep Working Group, include at least FIRST AUTHOR (Presenter), Mojtaba Zarei & Masoud Tahmasian (chairs), Paul M. Thompson (overall ENIGMA PI), LAST AUTHOR, on behalf of the ENIGMA Major Depressive Disorder Working Group. Of course other important contributors can be included as well.
3. If not all authors can be listed, consider putting in the abstract "Contributing Authors are listed at <http://enigma.usc.edu/ongoing/enigma-sleep-working-group/enigma-sleep-co-authors/>".
4. Regardless of the names listed on the abstract, it is best to list all contributors on the conference poster and/or the conference acknowledgement slide. PDF copies of the conference abstracts can be used by all ENIGMA Sleep members to list abstracts on CVs.

### **Symposium submissions:**

1. List the presenting author, and if possible, on behalf of the ENIGMA Sleep Working Group. Again, if possible consider putting in the abstract "Contributing Authors are listed at <http://enigma.usc.edu/ongoing/enigma-sleep-working-group/enigma-sleep-co-authors/>".
2. Regardless of the abstract, all contributors should be listed on the symposium talk acknowledgement slide.

### **Data Sharing**

If the project leader of the proposal agrees to the authorship and publication policies of the consortium the access request will be granted to the results files for those sites who have opted-in of the analysis and are a member of the Enigma Sleep working group or one of the Enigma Sleep working group PIs will be assigned as a project liaison. The liaison will be responsible for providing the data and answering any queries relating to the project, and providing the project leader with updates. The analysis plan will clearly state which variables will be included in the analysis, and thus what data is requested from each of the participating sites. The level of data-sharing will also be mentioned in the analysis plan, so that it is clear whether sites need to share raw imaging and/or genetic, individual structural or functional imaging measures derived from software packages including, but not limited to, FreeSurfer (hereinafter referred to as 'individual data'), or group-level summaries and post-estimation statistics.

The site PIs are responsible for ensuring anonymization of their site's MR and phenotypic data. Both the site PIs who contribute data to the project as well as the project leader are responsible to comply with all relevant rules and regulations imposed by their institutions. This may mean that the project needs to be approved or declared exempt by a committee that oversees research on human subjects, e.g. a local IRB or Ethics Committee. Depending on the existing ethical approval and the level of data sharing required by the project, sites may need to obtain additional approval for sharing anonymized data with the project leader. The project leader is required to



## ENIGMA Sleep Working Group “Analysis Plan Form”

keep track of ethical approval of each participating site when raw data or individual data needs to be shared for the project and will be able to provide this list when asked for, and include relevant information in the subsequent publication.

As not all ENIGMA Sleep participating sites are allowed or willing to share raw or individual data, and sharing data is explicitly not needed for joining ENIGMA, **a meta-analysis using group-level summaries and post-estimation statistics is preferred over a mega-analysis on raw or individual data.** When a mega-analysis framework is preferred to answer the question of interest in the proposed project, the project leader needs to specify why a meta-analysis approach is inadequate to answer the research question of interest and a mega-analysis approach is required for the proposed project.

The project leader is not allowed to share the data of participating sites to third parties **inside or outside the ENIGMA Sleep consortium.** These individuals shall all be named in the Analysis Plan. In case of sharing raw or individual data, the project leader keeps a document stating who has access to these data. Shall a cohort PI determine to withdraw from a project they had previously enrolled in and committed data towards, the project leader will comply and remove the dataset in question from all future analyses. Prior to this, all efforts would be made by ENIGMA-Sleep chairs to address any concerns the withdrawing PI may have and to determine if the project has deviated from proposed plans.



## ENIGMA Sleep Working Group “Analysis Plan Form”

### Appendix A: Analysis Plan

#### 1. Requestor Information

**Date of Submission:**

**Name:**

**Institution/Affiliation:**

**Email:**

**Have you signed and returned the ENIGMA Sleep Memorandum of Understanding?**

Yes/No\*

\*If no, please find the Memorandum of Understanding in the ENIGMA-Sleep website

**Funding (if applicable):**

#### 2. Analysis Plan

**Proposal Title:**

**First and senior authors and email addresses:**

**Co-author names and email addresses (initial list):**

*List the group of people who will be involved in the design, analysis and writing parts of the project, including their name, affiliation, role and email address. Please also include e.g. “In addition, all members of the ENIGMA-Sleep working group who contribute data for this project and edit the manuscript, will be coauthors.” to indicate that all ENIGMA members who contribute will be acknowledged.*

**Please list any potential conflicts of interest:**

**Give a brief summary of your analysis plan that includes the following:**



## ENIGMA Sleep Working Group “Analysis Plan Form”

### § Research questions and hypotheses

*Please be very specific regarding the research questions*

### § Brief background and rationale for addressing the research question within ENIGMA Sleep

### § Variables to be used in the analysis (the main predictor and outcome variables, and potential covariates must be identified)

*ad 1) what data is required in addition to what is already available in the database (e.g. additional variables in the Covariates.csv file, new or additional imaging measures, etc.)?*

### § Level of data sharing

*Please specify what level of data sharing is required. E.g. does the project involve raw scans, freesurfer (or other software or clinical) derived individual measures, group-level summary statistics, post-estimation statistics?*

*ad 1) In case sharing of raw scans or individuals measures is required for e.g. a **mega**-analytical statistical framework, please indicate why a **meta**-analytical approach using group-level summary statistics or post-estimation statistics is inadequate to answer the research question.*

*ad 2) In case sharing of raw scans or individuals measures is required for e.g. a **mega**-analytical statistical framework, please indicate where those scans and/or individual data will reside during the course of the project.*

*ad 3) In case sharing of raw scans or individuals measures is required for e.g. a **mega**-analytical statistical framework, please list the persons who will have access to those scans and/or individual data.*

### § Outline of analysis per research question

## 3. Timeline

**Timeline for completion and submission of manuscript:**

## 4. Resources

*Please describe what resources you can commit to the project - researcher time, troubleshooting, computational server time, helping writing and testing scripts, etc.*



## ENIGMA Sleep Working Group “Analysis Plan Form”

### Agreement

#### I hereby state that I agree that:

1. I will use the data only for addressing the research question described in point 2, and not for other purposes, unless I submit a new analysis plan.
2. I will comply with all rules regarding data sharing, publication and general policies stated in this data use agreement.
3. I will require anyone on my team who utilizes these data to comply with this data use agreement.
4. I will comply with all relevant rules and regulations imposed by my institution. This may mean that I need my research to be approved or declared exempt by a committee that oversees research on human subjects, e.g. my IRB or Ethics Committee. In addition, I will keep track of local ethical approval from sites participating in my project when sharing of raw or individual data is required.
5. If I publish conference abstracts, I will include the project chairs / major contributors, and as co-authors the ENIGMA Sleep working group chair, co-chair, overall ENIGMA PI, and the statement "on behalf of the ENIGMA Sleep Working Group" on the author line. If not all authors can be listed, I will include the phrase "Contributing Authors are listed at <http://enigma.ini.usc.edu/ongoing/enigma-sleep-working-group/enigma-sleep-co-authors/>" in the abstract to appropriately acknowledge all ENIGMA Sleep members who contributed to the project.
6. If I publish the manuscript, I will include the phrase "for the ENIGMA Major Depressive Disorder working group" on the author line of the manuscript, after the named authors. The ENIGMA Sleep website, i.e. <http://enigma.ini.usc.edu/ongoing/enigma-sleep-working-group/>, can be used as the affiliation.
7. I will acknowledge funding by NIH in the support acknowledgement section of the manuscript using language similar to the following:  

The ENIGMA-Sleep working group gratefully acknowledges support from the NIH Big Data to Knowledge (BD2K) award (U54 EB020403 to Paul Thompson).
8. I will submit the manuscript to the ENIGMA Sleep working group chairs prior to circulating it to all co-authors and prior to submitting to a journal. This review is intended to ensure that provisions described above are correctly implemented and to avoid overlap with other ENIGMA Sleep proposals/manuscripts. The ENIGMA Sleep working group chairs will maintain confidentiality of the manuscript and will complete its review within 2 weeks.
9. I will ask and document active approval of each co-author before submitting the article to a scientific journal.

Signed

Date, Location

\_\_\_\_\_

\_\_\_\_\_