** Guidelines data use NESDA**

Version 1.0 dd 10/12/2020, Harriëtte Riese en Brenda Penninx

*This document serves as a guideline for requesting access to, use of, and publication on data from*

*The Netherlands Study of Depression and Anxiety (NESDA)*

1. **Ownership of the data:**
   1. Under all circumstances, the data or any subset thereof will remain property of the NESDA consortium, represented by the NESDA principal investigator (PI) prof. dr. B.W.J.H. Penninx.
2. **NESDA publication plans:**
   1. As described in the *Consortiumovereenkomst*, all publication plans are submitted to the NESDA PI, prof. dr. B.W.J.H. Penninx. Twice a month (and once a month in vacation periods) the PI updates the NESDA board (i.e. local PI’s) on the submitted publication plans. One representative (Board member) from each site advises the PI within two weeks whether an application can be granted or rejected.
   2. For specific themes/data collections, there are a number of researchers with in-depth knowledge about each of the NESDA sub-studies. These researchers will act as *domain holders* within their sub-study. Domain holders are organised in committees who decide within two weeks whether an application can be granted or rejected. The respective domain holders for each topic are:  
      (1) EMA/actigraphy – dr. F. Lamers, dr. H. Riese, prof. dr. B. Elzinga, prof. dr. B.W.J.H. Penninx;  
      (2) Family study – dr. C.A. Hartman, prof. dr. B. Elzinga; prof. dr. B.W.J.H. Penninx

(3) fMRI – dr. M.J. Van Tol, prof. dr. N.J.A. Van der Wee, prof. dr. D.J. Veltman;

(4) Microbiome – dr. E.J. Giltay, dr. Y. Milaneschi;

(5) More domain holder groups can be formulated in the future.

1. **Authorship:**
   1. NESDA is a multicenter study, including sites in Amsterdam, Groningen and Leiden.

To join expertise and increase collaboration between the three sites, the first author is stimulated to invite a researcher from the other two sites to become coauthor on the publication plan. Depending on the content of the publication plan the researcher invited can be the PI, one senior researcher, a specific expert or a domain holder of a theme.

* 1. Invited co-authors will be given the opportunity to either become a co-author or suggest a co-author from their location because they were involved in the design and data collection or have relevant expertise or research interest.
  2. All co-authors will be involved in witting the publication plan before it is submitted for evaluation.
  3. The authorship positions are decided on at the start of the project in consultation with all co-authors. Changing the authorship positions, or including more co-authors, is allowed, but always in consultation with all co-authors.
  4. We follow the requirements for authorship and acknowledgements of the guidelines of the Committee of Medical Journal Editors ICMJE ([www.icmje.org/recommendations](http://www.icmje.org/recommendations)). This would e.g. indicate that if persons are listed as named authors on papers, but do not timely respond (i.e. within 3 weeks) to requests to review and/or do not respond that they need more time to review, they do not meet the authorship requirement and can be left out from the author list.
  5. All authors are responsible for all aspects of the paper.
  6. The first, second, and last author will take the lead in assuring that the publication plan is followed concerning the points under point 3a-e (“Give a brief summary of your analysis plan that includes the following”) in the NESDA analysis plan for which the data were provided. Publication costs for a specific publication are the responsibility of the last author.

1. **Requesting access to the NESDA and the decision process:**
   1. A publication plan for a project must be submitted to the NESDA administrator and the P.I. ([nesda@ggzingeest.nl](mailto:nesda@ggzingeest.nl) and [b.penninx@amsterdamumc.nl](mailto:b.penninx@amsterdamumc.nl)) by the researcher/research team requesting data. This publication plan has to be approved by the board or the domain holders before the data is provided. A template of a publication plan is available in Appendix A.
   2. Submitted publication plans will be evaluated on feasibility of the initiative and possible overlap with existing projects.
   3. A publication plan will be rejected if it is found to have substantial/complete overlap with existing project/project plans. If information is missing (typically variables requested or coding conform the NESDA codebook of the requested variables), or quality is insufficient, feedback will be provided and the authors can revise and resubmit an adapted publication plan.
   4. We strive to make a decision within 4-6 weeks (depending on time of the year) after submission of the request form.
   5. Before data can be made available by data-management, a data sharing agreement must be signed by the a designated representative of the Sponsor Institution (VUmc) and the most senior researcher from the applying researcher/team. This is not the case for researchers appointed at institutions that have signed the collaboration agreement *(Consortiumovereenkomst)* for NESDA.
   6. The requested data will be made available on the internal NESDA website to the applying researcher/research team if a publication plan is formally approved, and the data sharing agreement form is signed.
2. **Time Limitations:**
   1. The start date of any project depends on when the required data is available. If the project has not started after nine months, and renewed progress in the near future is deemed unlikely, the go-ahead may be revoked by the Board members and the plan retracted.
3. **Usage of the data and publishing about the data:**
   1. One can only publish a paper about the data and research questions if research questions, design, analyses, and authorships are consistent with the publication plan form and if all authors have approved the final version of the paper before submission.
   2. If changes to the publication plan are made during the research process, an ‘amendment’ to the publication plan needs to be written and submitted for approval.
   3. NESDA data may never be published in any public space (such as online repositories), as true anonymity of the data can never be guaranteed given this type of data.
   4. The naming of variables, calculations based on variables, and the use of certain definitions in the publication should be consistent with previous NESDA papers using the same data,unless convincing arguments are given in the paper to deviate. Examples:
      * 1. *an item named self-esteem cannot be referred to as measuring self-efficacy in another paper.*
        2. *the calculation of a factor (mean score) based on different items (e.g. ‘negative affect’) cannot be done differently in the new paper compared to a previous paper without motivation.*
   5. Every paper should describe that the study was approved by the Medical Ethical Committee of the VUmc (reference number 2003/183), and that written informed consent was obtained from all participants.
   6. Every paper should list the baseline sample of NESDA (n=2981) and clearly explain how possible subsamples used in papers are derived.
   7. Every paper on the NESDA data should include an acknowledgement, namely: “ *The infrastructure for the NESDA study (*[*www.nesda.nl*](http://www.nesda.nl) *) has been funded through the Geestkracht program of the Netherlands Organisation for Health Research and Development (ZonMw, grant number 10-000-1002) and by participating universities and mental health care organizations (Amsterdam University Medical Centers (location VUmc), GGZ inGeest, Leiden University Medical Center, University Medical Center Groningen, University of Groningen, Lentis, GGZ Friesland, GGZ Drenthe, Rob Giel Onderzoekcentrum).*
   8. For specific types of data that have been obtained through other funding resources (e.g. inflammation markers, telomere length, DNA or RNA data), additional acknowledgements are required. These will be communicated through the project office.
   9. The last author is responsible for adhering to 6.5, 6.6, 6.7 and 6.8. If the last author is not a senior NESDA investigator, the paper should be checked by the senior NESDA investigator indicated on the publication plan before submitting for publication.
   10. In case the NESDA data are used for a Master Thesis the senior NESDA investigator is responsible for preventing that the Master Thesis is submitted into a public online depository (as is e.g. a default procedure at some universities/Research schools). Editors/journals may consider such online publications as a restriction to subsequently publish the work in their journal. When NESDA data are used for a Master Thesis, and it is the intention that a resulting manuscript will be submitted for publication in a (international) journal, this needs to be indicated as such on the analysis plan. If this was not originally the case, but over time the co-authors change their opinion and do plan for publication, they need to re-adjust the analysis plan on this aspect and inform and get reapproval by the project office. When there are no current or reasonable future plans for publishing in a journal the Master Thesis may be suitable for online publication; always contact the project office for approval in these cases.
4. **Preregistration and Preprints**

7.1. When authors want to preregister their NESDA data analysis plan on a public repository, they are allowed to do so *after* approval of the data analysis plan. The last author of the paper (senior investigator) is responsible for following the procedure in the correct way, this includes mentioning the preregistration in the final version of the manuscript and updating the preregistration in case the NESDA analysis is retracted.

7.2. Publishing preprints of a the final version of a manuscript that is submitted for considering for publication in a journal is possible when i) the data analysis plan has been approved, ii) all co-authors are informed and consent with publishing the preprint. It should be made clear to all coauthors that *not all scientific journals will accept a manuscript* for considering for publication when the manuscript is published as a pre-print. This therefore requires careful consideration.

1. **After your NESDA paper has been published**
   1. Mail the pdf to NESDA’s project office ([nesda@ggzingeest.nl](mailto:nesda@ggzingeest.nl)). The name of the pdf file should include the date and last name of the first author as follows: NAME\_Journal\_yyyy.pdf . In addition, hand-in DOI, and key words for search function on the NESDA website. Possible keywords are; clinical, social, biological, psychological vulnerabilities, imaging, genetic psychiatry, genetic other, patient care, other, EMA/actigraphy, Sibling study.
   2. Newly derived variables used in NESDA papers (e.g. established factor scores, summary scores, new concepts) need to be archived through the Data documentation Committee ([nesda@ggzingeest.nl](mailto:nesda@ggzingeest.nl)). This Committee, represented by all three main sites, supervises the storage and documentation of new variables and makes certain that these newly derived variables can be re-distributed for other researchers through data management.
   3. You may be asked to mail the final syntax/scripts of your analysis to datamanagement. The name of the script files should include the date and last name of the first author as follows: yyyymmdd\_NAME.ext
   4. You may be asked to write a Dutch/English summary of your NESDA publication for a press release, an item for the NESDA newsletter, or a Twitter message.

**Appendix A - Template NESDA publication plan version, dd 14-02-2020**



**NESDA ANALYSIS PLAN**

Please e-mail the completed form to NESDA, Oldenaller 1, 1081 HJ, Amsterdam.

E-mail: [nesda@ggzingeest.nl](mailto:nesda@ggzingeest.nl) and [b.penninx@amsterdamumc.nl](mailto:b.penninx@amsterdamumc.nl)

l: [brendap@ggzba.nl](mailto:brendap@ggzba.nl)

Number: Date of receipt: Date of approval:

1. **First author information:**

Name of first author:

E-mail address:

Telephone:

Site where the first author is formally affiliated to (multiple options possible)

: □ LUMC □ UL\* □ UMCG □ RUG\* □ VUMC □ VU\* □ GGZinGeest

□ Other\* namely: ……….

\*for these sites a signed Data Sharing Agreement (DSA) is required before data access can be granted. Routing and signing of a DSA is done after a data analysis plan is approved.

Which NESDA senior investigator will supervise?:

If there is specific funding for the conduct of data analyses, please mention:

1. **Working title of plan:**

This analysis will be used for (delete the sentences not applicable):

* A (master) thesis, not leading to a paper and not publicly available
* A paper based only on NESDA data, that will be published in a scientific journal
* A paper part of a larger initiative of which NESDA is one of the participating studies.

Please specify the larger initiative or consortium:

1. **Give a brief summary of your analysis plan that includes the following**:
2. Research question and hypothesis
3. Brief background and rationale for addressing the research question in NESDA
4. Describe what has been done in NESDA in this area, and how this current plan extends earlier findings and does not have overlap with earlier analyses/papers
5. Variables and Wave of data collection to be used in main analysis (main predictor, main outcome and covariates all need to be identified in detail)
6. Outline of analyses
7. **Proposed authors:**
8. **Timeline for completion and submission of manuscript:**

**I hereby state that I will use the data only for addressing the research question described in point 3, and not for other purposes, unless I submit a new analysis plan.**

Signed Date

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**Appendix B - Instruction template NESDA publication plan**

1. **First author information:**

Provide the details asked for. A NESDA senior investigator is defined as a person who is member of the NESDA board or one of the domains (NESDA sub-studies).

1. **Working title of plan:**
2. **Give a brief summary of your analysis plan that includes the following**:
3. *Research question and/or hypothesis*

Describe all aims and hypotheses to be examined as explicitly as possible, while remaining specific and concise. If multiple predictions can be made for the same research question, describe what would be expected based on different theories. If the paper concerns exploratory questions, please describe what type of hypotheses will be generated by the paper.

1. *Brief background and rationale for addressing the research question in NESDA*

Please include a problem statement.

1. *Describe what has been done in NESDA in this area, and how this current plan extends earlier findings and does not have overlap with earlier analyses/papers*

Here it is important to indicate you are familiar with prior NESDA studies and what this paper adds to related NESDA project plans/publications. This information is also relevant for your final publication and needs to be checked prior submission of the manuscript by the NESDA senior investigator.

1. *Variables and Wave of data collection to be used in main analysis (the main predictor and outcome variables must be identified)*

List all variables needed for the analyses / description in the paper. Only those will be provided.

1. *Outline of analyses*

Describe

1. Analysis inclusion criteria based on demographics, disease status, outliers, missingness, or others.

2. Pre-processing steps: handling of missing data, testing of assumptions such as variability in the data -including plans for alternative/corrected analyses if each assumption is violated, use of factor scores, variable transformations, power analysis.

3. Analyses: the statistical technique, each variable’s role in the technique (e.g., independent variable, dependent variable, moderator, mediator, covariate), rationale for each covariate used (incl refs) if any; if using techniques other than null hypothesis testing (for example, Bayesian statistics), describe your criteria and inputs toward making an evidential conclusion, including prior values or distributions.

1. **Proposed authors:**

Provide the names and order of your co-author. All co-authors should be acknowledged of point 3 (Authorship) of the ‘Guidelines data use NESDA’.

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

Indicate expected timeline. Generally, we assume that 9 months should be adequate to progress on analyses. If not, you can be notified that an approved analysis plan is expired e.g. in case of existing competing interests.

**Appendix C – Data-Use Agreement for not NESDA sites**

**DATA SHARING AGREEMENT**

The parties identified below hereby agree to be bound by the terms set forth hereunder.

**Definitions Meaning**

|  |  |  |
| --- | --- | --- |
| **Supplier**  *party supplying the Data* | **VU University Medical Center**, part of Foundation VUmc, with registered address at De Boelelaan 1117, 1081 HV Amsterdam, the Netherlands, legally represented by Anne Zijtregtop, Manager Division 5 | |
| **Recipient**  *party receiving the Data* | [XXXXXXX], having its office at [XXXXXXX], legally represented by [XXXXXXX] | |
| **Whereas**  *reasons why this agreement is concluded, context* | To collaborate on NESDA data around the theme:  XXXXXX – Add title of NESDA analysis plan here | |
| **Term**  *after what term should the Data be irreversibly deleted?* | Two years | |
| **Data**  *please describe which data is provided other than personal data (type, amount, format, etc). Personal data is described below.* | A detailed data analysis plan is attached in Appendix 1. This describes the needed data variables and waves that are required. | |
| **Personal data** *which categories of Personal data are provided?* | Pseudonymised personal data | |
| **Special Categories of Personal data**  *does the Data contain any of the following types of personal data?* | racial or ethnic origin  political opinions  religious or philosophical beliefs  trade union membership  genetic data | biometric data for the purpose of uniquely identifying a natural person  data concerning health  data concerning a natural person's sex life or sexual orientation |
| **Data subjects** *from which categories of data subjects is the Data derived? (e.g. students, athletes, patients, researchers, etc)* | Research participants from the NESDA cohort (psychiatric patients as well as controls) | |
| **Purposes**   *why this the Data provided to  Recipient? Please explain for which purposes the Data will be used.* | A detailed analysis plan is attached in Appendix 1. | |

**other information**

|  |  |  |
| --- | --- | --- |
| **Does the Personal data only contain Pseudonymised data?**  *if the Personal data contains data which is not Pseudonymised or coded, check “no”* | yes  no | |
| **Will the Personal data be transferred outside the European Economic Area (EEA)?** | yes  no | |
| **Contact points for data protection enquiries** | **Supplier**  Name: Brenda Penninx  Job title: PI NESDA  Telephone: +31 20-7885674  E-mail: b.penninx@amsterdamumc.nl | **Recipient**  Name:  Job title:  Telephone:  E-mail: |

All fields above are mandatory and must be filled in.

|  |  |
| --- | --- |
| **Signature authorized representative Supplier** | **Signature authorized representative Recipient** |
| Name: Anne Zijtregtop  Title: Manager Division 5 (VUmc)  Signature:  Date: | Name:  Title:  Signature:  Date: |

Supplier and Recipient are solely referred to as “**Party**” and collectively referred to as “**Parties**”.

Now, therefore, in consideration of their mutual promises to each other, hereinafter stated, the Parties agree as follows:

**Definitions**

1. “**Data**” means the data as identified on page one above which the Supplier will transfer to the Recipient. The Data will contain Personal data as identified on page one.
2. “**Confidential Information**” means any proprietary information, know-how, data, or procedure related to the Data and disclosed by Supplier to Recipient pursuant to its rights or obligation under this Agreement.
3. “**Controller**”, “**Data subject**”, “**Personal data**”, “**Processing**”, “**Processor**”, “**Personal data breach**” and “**Supervisory authority**” shall have the meaning as in the General Data Protection Regulation (EU) 2016/679 (hereinafter: “**GDPR**”).
4. “**Pseudonymised data**” means Personal data which can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the Personal data are not attributed to an identified or identifiable natural person.

**Clause 1. The Processing of Personal data**

* 1. The Supplier will provide the Recipient with the Data in accordance with the terms of this Agreement, for the Purposes.
  2. Insofar Personal data within the meaning of the GDPR are provided by the Supplier to the Recipient and/or Processed by the Recipient, both the Supplier and the Recipient qualify as independent Controllers for such Processing. For the avoidance of doubt, this data sharing agreement is not an agreement as meant in article 26.1 nor article 28.3 of the GDPR. Descriptions of the Data subjects, the Purpose of the transfer and the Special Categories of Personal data are included on page one.
  3. The Supplier warrants and undertakes that:

1. the Personal data have been collected, processed and transferred in accordance with the GDPR and any other applicable data protection laws;
2. it has obtained any regulatory or ethics approvals necessary to collect the Data and transfer the Data to the Recipient.

1.4 The Recipient warrants and undertakes to:

1. process the Personal data in accordance with the GDPR and any other applicable data protection laws;
2. only use the Data for the Purposes;
3. not carry out any procedures with the Personal data (such as linking and comparing) through which the identity of the Data subject could be derived;
4. have in place appropriate technical and organisational measures to protect the Personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected;
5. without prejudice to any other contractual obligation to confidentiality that applies, treat all Personal data as strictly confidential and inform all of its employees, representatives and/or (sub)Processors who are involved in the Processing of the Personal data of the confidential nature of such information and of the Personal data. The Recipient will ensure that such persons and the Parties have signed an adequate confidentiality agreement;
6. immediately notify the Supplier after it has reported a Personal data breach to a Supervisory authority and/or the Data subjects in connection with Personal data that it has received from the Supplier. In such case, the Recipient will contact the Contact point of the Supplier as specified on page one;
   1. If the Personal data are processed or transferred in or to countries outside of the European Economic Area (EEA) which are not determined by the European Commission to ensure an adequate level of protection within the meaning of article 45 of the GDPR, Parties enter into the Standard Contractual Clauses set out in in **Annex 1** to this Agreement. In the event of any conflict or inconsistency between this Agreement and the Standard Contractual Clauses, the Standard Contractual Clauses prevail. If the Court of Justice of the European Union or a Supervisory authority or similar governmental authority determines that the Standard Contractual Clauses are not a lawful method to facilitate transfers of Personal data oustide of the EEA, the Parties shall negotiate in good faith an alternative method to facilitate such transfers.

**Clause 2. Confidentiality**

2.1 Confidential Information shall be used by the Recipient solely for the Purposes. The Recipient agrees not to disclose Confidential Information to third parties without the consent of the Supplier and under an agreement by the third party to be bound by the obligations of this clause 2. The Recipient shall safeguard Confidential Information with the same standard of care that is used with Recipient’s own confidential information, but in no event less than reasonable care.

The Data is not considered to be Confidential Information as clause 1.4 section e already obliges the Recipient to keep the Data confidential. This clause 2 concerns other information which may be shared between the Parties and the obligation to keep such information confidential.

* 1. The obligations under this clause 2 shall not extend to any information:
* which is or becomes publicly available through no breach of this Agreement;
* which Recipient can demonstrate that it possessed free of any obligation of confidence prior to, or developed independently from, disclosure under this Agreement;
* which Recipient receives from a third party which is not legally prohibited from disclosing such information; or
* which Recipient is required by law to disclose.

2.3 The obligations of this clause 2 shall survive this Agreement for a period of three (3) years after termination or expiration of this Agreement. Upon the request of the Supplier, the Recipient agrees to return the Confidential Information to the Supplier or destroy, at the option of the Supplier, all copies of Confidential Information; provided, however, that Recipient shall be entitled to retain one copy of Confidential Information solely to ensure compliance with its rights and obligations hereunder.

**Clause 3. Results**

3.1 All discoveries, developments, databases, inventions (whether patentable or not), methods, reports, know-how, or trade secrets which are made by the Recipient as a result of the conduct of the Purposes (hereinafter: “**Results**”) shall be the solely property of the Recipient.

3.2 The Recipient shall grant the Supplier a non-exclusive and non-sublicensable license to utilize all such Results for all non-commercial research and educational purposes.

**Clause 4. Publication**

4.1 Parties will jointly publish the Results in one or more articles in peer reviewed journals. Parties will not publish the Results independently.

4.2. Recipient will credit Supplier appropriately in the publication as the supplier of the Data.

**Clause 5. Representations and warranties**

5.1 Other than the warranties set out in section 1.3, the Data is provided by the Supplier to the Recipient without any warranties whatsoever, express or implied, including any warranties for merchantability or fitness for a particular purpose.

5.2 The Recipient represents and warrants that the Data shall be used and the Purposes shall be performed in accordance with this Agreement, Consent and all applicable local and international laws and regulations.

5.3 Nothing in this Agreement shall be construed as granting to Recipient, either expressly or by implication, any right or licence to the Data, under any patent, patent application, trade secret, know how, confidential information, trade or service mark, copyright, or other intellectual and/or industrial property rights Supplier possesses or may possess, nor any option to any such right or license.

**Clause 6. Liabilities and indemnification**

6.1 The Recipient assumes the risk of any damage, loss, or expense associated with or resulting from the conduct of the Purposes or Recipient’s use of the Data, unless such damage or loss is caused by the gross negligence or wilful misconduct of the Supplier.

6.2 The Recipient will indemnify and hold the Supplier, its directors or employees harmless against all claims of any kind whatsoever that may arise or result from the use of the Data.

6.3 The Supplier shall not be liable toward the Recipient for any claims, costs or damages that may result, directly or indirectly, out of Recipient’s use of the Data and/or Results, unless and to the extent that damage is caused by gross negligence and/or due to wilful misconduct by the Supplier.

6.4 The Parties shall in no case be liable for any indirect, incidental or consequential damages (including without limitation, lost business or profits, or loss of use of equipment) suffered by another Party.

**Clause 7. Duration and termination of the Agreement**

7.1 This Agreement shall become effective on the date of the last Party’s signature below, and shall remain for the duration of the Term as identified on page one above, unless terminated earlier in accordance with section 7.2. The Parties agree that the term may be extended by mutual written agreement.

7.2 This Agreement can be terminated earlier by either Party with immediate effect by receipt of written notice:

a. Upon a material breach of this Agreement by the other Party, if it is not cured within thirty (30) days after the breaching Party has received written notice of such material breach.

b. in the event the other Party is in state of bankruptcy or suspension of payment or a petition to that effect is filed by or against that Party;

c. in the event the business of the other Party will be winded up or closed down;

d. in case of force majeure - as determined in clause 11 below - if the force majeure situation will last over ninety (90) days.

7.3 The Recipient agrees, on termination of this Agreement (whether as a result of its breach or otherwise) to cease all use of the Data and shall within fifteen (15) days return all Data to Supplier or destroy all Data at the sole discretion of Supplier, or to deal immediately with the Data in accordance with Supplier’s written instructions.

7.4 Clauses 1, 3 -6, 8 and sections 7.4 shall survive expiration or early termination of this Agreement, as well as any terms that by their nature would be expected to survive expiration or early termination of this Agreement shall survive such expiration or early termination. Clause 2 will survive expiration or early termination of this Agreement for the term specified in clause 2.

**Clause 8. Publicity**

Neither Party will use the logo or name of the other Party or the name of an employee of the other Party, for promotional purposes, in any publicity, advertising or news release, without prior written approval of the Party whose name is to be used.

**Clause 9. Modifications**

Modifications, changes and extensions to this Agreement are only binding after these have been agreed upon in writing between the Parties.

**Clause 10. Assignment**

The rights and obligations as determined in the Agreement may not be assigned by a Party without the prior written consent of the other Party, which consent shall not be unreasonably with­held or delayed.

**Clause 11. Force Majeure**

In case of force majeure the concerning Party is entitled to suspend the obligations for the duration and extent of the force majeure, provided that the other Party has been notified in writing of the force majeure. Force majeure situations will concern those situations which prevent the execution of the Agreement and which are not imputable to the concerning Party pursuant to law, Agreement or according to generally accepted standards and as a result will not be attributable to that Party.

**Clause 12. Severability**

The invalidity or unenforceability of any particular provision of this Agreement shall not affect any other provisions therein. The Agreement shall be construed in all respects as if such invalid or unen­forceable provision were omitted.

**Clause 13. Governing law**

13.1 This Agreement will be governed by Dutch law.

13.2 In the event a disputes may arise from the Agreement, or from the execution of the Agreement, Parties will first try to settle such dispute amicably. If the dispute cannot be settled amicably, it will be submitted to the competent court in the district of Amsterdam, the Netherlands.

**Clause 14. General Terms and conditions**

No general conditions will apply to this Agreement.

**IN WITNESS WHEREOF**, the Parties hereto have by their authorized represen­tative duly caused this

Agreement to be executed. Signatures are placed on page 2.

**Annex 1 NESDA Data analysis plan**

**ADD (COPY-PASTE) HERE ANALYSIS PLAN**