**Agreement for the use of Stichting HIV Monitoring data**

[INSTITUTION], with its registered office at [STREET], [PLACE], Chamber of Commerce No [CoC number], legally represented by [NAME e.g. head of department/division], (hereinafter: **Institution**),

and

Stichting HIV Monitoring (SHM), with its registered office at Meibergdreef 9, 1105 AZ Amsterdam, Chamber of Commerce No 34160453, legally represented by S. Zaheri, and M. van der Valk, Board of SHM, (hereinafter: **SHM**),

enter into this agreement (hereinafter: **Agreement**) to arrange the use of SHM data for research purposes.

The following form an integral part of the Agreement:

a) Statement concerning the use of SHM data

b) Appendix 1: General Terms and Conditions

c) Appendix 2: Description of the Study and the Data

d) Appendix 3: Statement on data transfer upon completion or discontinuation of the study

**Statement concerning the use of SHM data**

The Institution guarantees that the data provided by SHM to the Institution in connection with the study [RESEARCH TITLE and NUMBER] (hereinafter: **Data**) will exclusively be used for the above-mentioned study (hereinafter: **Study**), executed by [NAME STUDY APPLICANT]. A description of the Study and Data is provided in Appendix 2.

Under no circumstances will the Data, in whatever form, be used for any purposes other than for the Study or be disseminated by any means or disclosed to third parties. When the Data are no longer required for the study or, in any event, when the study is completed, the Institution will notify SHM accordingly by email as soon as possible but within no more than one month at the latest. After this notification, SHM will notify the Institution that the received Data can be destroyed and/or transferred. After this notification from SHM, the Institution will destroy all original SHM Data and all copies of any related documents without delay, excluding the analysis data set that is required to reproduce results of the research. A copy of this analysis data set will be shared with SHM. The Institution will then send SHM a signed “Statement regarding data transfer upon completion or discontinuation of the study”, as contained in Appendix 3, as soon as possible but within no more than one month. This statement can be signed on behalf of the Institution by the Study project leader.

The Institution will provide SHM with a copy of all reports (such as poster presentations or publications) that have been published or will be published using the Data.

SHM will retain the original Data for a statutory retention period after publication, in conformity with the Medical Research Involving Human Subjects Act (WMO) and the guidelines of the Central Committee on Research Involving Human Subjects (CCMO). The Institution is responsible for the proper reporting of the data analysis and the retention of the syntaxes/scripts that were written to carry out the analyses and obtain the research results.

The Institution guarantees that anyone using the Data in connection with the Study has read and understood the contents of this statement.

Signed at………………… date ……………………

Institution:

…………………………

[NAME OF Institution Legal Representative e.g. head of department/division]

SHM:

Signed at………………… date ……………………

…………………………

M. van der Valk (Board)

Signed at………………… date ……………………

…………………………

S. Zaheri (Board )

Appendix 1: **General Terms and Conditions**

The Institution and SHM can also be referred to separately as ‘**Party**’ and jointly as ‘**Parties**’.

**Article 1. Provision of Data**

1.1. Pursuant to the Agreement, SHM will provide Data, including personal data, to the Institution, thereby granting the Institution the right to use these Data.

1.2. Terms from the General Data Protection Regulation (hereinafter: **GDPR**), such as “processing”, “personal data”, “data controller”, “processor” and “third party”, have the same meaning as in the GDPR.

1.3. The Institution guarantees that it shall exclusively use the Data received from SHM for the purpose described in the Agreement. Other processing operations will exclusively be performed if explicitly agreed between Parties or required by law.

1.4. SHM will protect the files containing the Data with a password using 7zip and send these files via filesender, and also instructs the Institution to make use of filesender for sending the Data. SHM will support this by sending the Institution an invitation for the use of filesender. If the foregoing is not reasonably possible for the Institution, Parties will jointly agree on an alternative acceptable method for the provision of Data in conformity with the GDPR.

**Article 2. Obligations of Parties**

2.1. Parties declare mutually that the processing of the provided personal data pursuant to the Agreement will take place in a proper and careful manner. Each Party must, in its capacity as data controller within the meaning of Article 4 (7) of the GDPR, ensure that the processing operations taking place under its responsibility comply with the applicable laws and regulations.

2.2. The provided Data must be used by the Institution in a scientifically responsible manner in accordance with the Dutch Academic Integrity Code. (http://www.vsnu.nl/files/documents/Netherlands%20Code%20of%20Conduct%20for%20Research%20Integrity%202018.pdf).

2.3. The Institution ensures that the storage and processing of personal data obtained from SHM will take place in strict separation from the personal data that it processes for itself or for third parties.

2.4. All personal data supplied between Parties are subject to an obligation of secrecy towards third parties.

2.5. This obligation of secrecy is not applicable insofar as the Party providing the data has given consent to provide the information to third parties, or if the provision of the information to third parties is logical and necessary in view of the purpose for which the personal data were provided and/or for the fulfilment of this Agreement, or if the information must be disclosed to a third party pursuant to a statutory obligation or court ruling.

2.6. The obligations arising from Article 2 also apply to those who process personal data under the authority of the Parties, including, but not restricted to, employees in the broadest sense of the word.

2.7. If the Institution outsources any part or parts of the initial or further processing of the provided personal data to a processor, it will ensure that the processor processes the personal data in a proper and careful manner and in accordance with the applicable laws and regulations. Arrangements concerning the processing of personal data by a processor will be recorded in a suitable processor agreement. At the request of SHM, the Institution will provide insight into these processor agreements as well as a full list of the processors used by the Institution, including the countries these processors are situated in.

2.8. SHM endeavours to ensure that it does not provide more personal data to the Institution than necessary to achieve the intended purpose of the provision of information.

2.9 SHM endeavours to anonymize or pseudonymize the personal data insofar as possible or to make the personal data as untraceable as possible before their provision to the Institution.

2.10 The Institution guarantees that any Data linked to traceable personal data will not leave the Institution. SHM may carry out checks to ensure compliance with this provision and, in the event of actual or suspected non-compliance, may challenge the relevant employee of the Institution, such as a researcher or student, and report incorrect usage of SHM’s patient codes.

**Article 3. Security**

3.1. Each Party undertakes to ensure the security of personal data falling under their responsibility.

3.2. The Institution will implement and maintain sufficient and suitable technical and organizational security measures. Taking account of the nature of the personal data, the risk of the processing operations to be performed, available technology and implementation costs, these security measures will ensure an adequate level of protection to safeguard the personal data against any form of unlawful processing (such as unauthorized access, corruption, alteration or disclosure). These measures shall at least include (but are not restricted to):

a) storage of the Data on a computer or laptop that is protected with a strong password, effective virus scanner and firewall;

b) measures ensuring the physical and logical security of the Data;

c) measures ensuring that only authorized persons have access to the Data;

d) measures protecting the Data against accidental or unlawful destruction, accidental loss or alteration, unauthorized or unlawful storage, processing, access or disclosure;

e) measures preventing negligence or intentional improper use of the Data by employees.

3.3. The Institution will at all times have an effective written data protection policy for the processing of personal data, which will at least set out the measures mentioned in paragraph 2 of this Article 3. SHM has the right to check or instruct a third party to check compliance with the measures mentioned above under 3.2 and 3.3. The Institution will, at SHM’s request, provide an opportunity for such a compliance check at least once a year at a time to be agreed between Parties as well as on any other occasion that SHM may consider this appropriate in view of actual or suspected information or privacy incidents.

3.4. The Institution acknowledges that security requirements are subject to continuous change and that frequent evaluation and regular improvement of obsolete security measures is crucial to achieve effective security. The Institution will therefore evaluate, adjust, supplement and improve the measures on an ongoing basis in order to continue meeting its obligations under this Article 3.

**Article 4. Reporting of Data Breaches**

4.1. Parties are and remain independently responsible for reporting any data breaches that take place under their responsibility to the Personal Data Authority and/or the data subjects. A data breach is defined as: a security incident leading to the accidental or unlawful destruction, loss or alteration of Data or the unauthorized disclosure of or access to Data that have been transmitted, stored or otherwise processed within the meaning of Article 4 (12) of the GDPR.

4.2. The Institution is, without prejudice to the other obligations set out in this Article, obliged to reverse or minimize any negative consequences arising from a data breach as promptly as possible.

4.3. Parties will notify each other of an identified data breach relating to the data as mentioned under Article 4.1 within 24 hours of discovery. The Party nominated as data controller within the meaning of the GDPR is responsible, in conformity with the provisions of the GDPR, for deciding whether and how the Personal Data Authority and the data subjects must be informed. If the data subjects must be informed, Parties will discuss the best way to proceed with each other. Parties will assist each other to the best of their ability in this connection and will share all relevant information.

**Article 5. Attribution Rules**

5.1Submitted or published Articles must refer to Stichting HIV Monitoring and the Ministry of Health, Welfare and Sport, and the ATHENA cohort must be added as group author: "on behalf of the ATHENA observational HIV cohort" and "The ATHENA database is managed by Stichting HIV Monitoring and supported by a grant from the Dutch Ministry of Health, Welfare and Sport through the Centre for Infectious Disease Control of the National Institute for Public Health and the Environment". In addition, SHM acknowledgements must be included as an appendix; these will be provided by SHM on request.

**Article 6. Data Subject Rights**

6.1 A Party will independently handle a request from a data subject within the meaning of Section 3 of the GDPR if said Party is the data controller for the requested processing operation.

6.2 A Party who receives a request (as mentioned in the preceding paragraph) for a processing operation for which it is not the data controller will forward the request to the Party that is the data controller for the requested processing operation. The data subject who submitted the request may be sent notification of this.

6.3 Parties will provide each other with all necessary information and assistance to enable the other Party to handle the request (as mentioned in paragraph 1).

**Article 7. Supervision and non-compliance**

7.1 On request, the Institution will provide SHM with all information on the manner in which the Agreement was fulfilled as well as access to all related Data and documents.

7.2 If the Institution acts in breach of this Agreement or any applicable laws or regulations, SHM can suspend or withdraw the right to use the Data as described in Article 1 (1) and claim compensation for damages.

**Article 8. Liability**

8.1 SHM will make every effort to meet its obligations arising from this Agreement and accepts statutory obligations to pay compensation insofar as provided for in this Article.

8.2 SHM is exclusively liable in the event of a culpable failure to meet its obligations arising from this Agreement and exclusively for direct damage up to a maximum amount of €10,000 (ten thousand euros).

8.3 Direct damage is damage arising from a culpable failure to fulfil this Agreement and will exclusively consist of the compensation for damage resulting directly from said failure, i.e. compensation of the value of the action that was not performed (replacement compensation) up to the maximum amount mentioned in the preceding paragraph.

8.4 SHM rejects all liability for any other form of damage, including additional compensation in whatever form, compensation for indirect loss or consequential loss or compensation for lost revenue or profit or data loss. Nor is SHM liable for mistakes made by the Institution or those working under the authority of the Institution, or for damage resulting from the provision of incorrect or incomplete information by the Institution.

8.5 SHM is under no circumstances liable for any damage arising from delays, damage arising from loss of business details or the supplied data, damage arising from failure to meet deadlines as a result of changed circumstances, damage arising from the provision of inadequate cooperation or information by the Institution, or damage arising from information, research reports or advice provided by SHM whose content does not form an explicit part of this Agreement.

8.6 Any restriction or exclusion of liability provided for in this Agreement does not apply if the damage results from deliberate intent or conscious recklessness of the SHM or the Institution.

8.7 The Institution is liable for any damage arising from the non-performance of this Agreement or from any other further conditions agreed in connection with this Agreement.

8.8 The Institution indemnifies SHM against all claims from third parties (including data subjects) and will compensate SHM in full for any loss arising from such claims.

8.9 Any entitlement to compensation is subject to the condition that the Institution reports the damage to SHM in writing within 30 days of discovering the damage.

**Article 9. Force majeure**

9.1 SHM cannot be required to fulfil any obligation under this Agreement if this is prevented by force majeure. SHM is not liable for any damage arising from force majeure.

9.2 Force majeure at least includes power failures, internet failures, telecom infrastructure failures, network attacks (including DoS/DDoS attacks), malware or other malicious software, civil unrest, mobilization, war, import and export restrictions, strikes

stagnating supply, fire and flooding, as well as cases where SHM is unable to fulfil the Agreement due to supplier failures, irrespective of the reason for said failures.

9.3 During this period, the Institution is not entitled to claim damages for any non-performance of the Agreement that is attributable to force majeure. The above does not affect any payment obligations relating to damage that is not directly or indirectly attributable to force majeure. Prolonged force majeure does not entitle the Institution to terminate this Agreement.

**Article 10. Disputes**

10.1 Parties will make every effort to find an appropriate solution for any disputes that may arise regarding the fulfilment of the Agreement. If the Parties are unable to resolve the matter, they will set up a disputes committee consisting of one member nominated by the Institution and one member nominated by SHM. These two members will nominate a third person to act as independent member and chairperson. If either Party disagrees with the verdict of this disputes committee, the dispute can be put to the competent court in the district where SHM is established.

**Article 11. Progress Report**

11.1 SHM expects to receive a progress report from the project leader at the start of each year, which will be published in SHM’s annual report. The project leader receives a template which must be completed for this purpose within 4 weeks after notification. The report must at least contain the following information:

a) summary of the progress, including background, methods, results and conclusions;

b) a list of publications in peer-reviewed journals or other printed publications originating from the research project; and

c) summaries of presentations, authors, date and place of presentation.

**Article 12. Duration and termination of the Agreement**

12.1 This Agreement commences on the date of signature by both Parties and is entered into for the period of the Study.

12.2 This Agreement ends automatically if the recognition of SHM as an HIV monitoring organization is ended and/or if SHM is dissolved.

12.3 This Agreement ends automatically if the Institution is declared bankrupt, requests suspension of payments, has all its assets placed under attachment, or is liquidated or dissolved.

12.4 The Agreement can only be terminated by both Parties jointly. Early termination of the Agreement does not in any way release Parties from any obligations arising from this Agreement that are intended to continue after the termination of the Agreement.

**Article 13. Other provisions**

13.1 Parties may only amend this Agreement with mutual consent and will make every effort to make appropriate amendments to this Agreement whenever necessary as a result of legal or regulatory amendments.

13.2 If any provision in this Agreement proves to be invalid, this will not affect the validity of the entire Agreement. Parties will make every effort to replace the invalid

provisions with new valid provisions that approximate the intention of the invalid provisions and this Agreement insofar as possible.

13.3 The logs and communications with the Institution as stored by SHM are deemed to be correct unless the Institution provides proof to the contrary.

13.4 This Agreement and its performance are governed by Dutch law.

13.5 In the event of any conflict between different agreements or their appendices, the order of precedence shall be as follows:

a) the Statement concerning the use of SHM data

b) these General Terms and Conditions (Appendix 1)

c) any other agreements or conditions.

Appendix 2: **Description of the Study and Data**

In connection with the following study:

[DESCRIPTION OF STUDY, SUCH AS RESEARCH TITLE AND NUMBER]

SHM shall provide the following Data to the Institution:

[DESCRIPTION OF DATA]

Appendix 3: **Statement regarding data transfer upon completion or discontinuation of the study.**

[INSTITUTION] (hereinafter: the Institution) declares that all SHM data received by the Institution in relation to the study

[STUDY + STUDY NUMBER], started on [DATA RECEIPT DATE] and ended on [RESEARCH END DATE],

were destroyed on [DATE].

- After the completion or discontinuation of analyses performed by the Institution, the Institution destroyed all original SHM data that were provided to the Institution in connection with the abovementioned study.

- The Institution has exclusively retained the analysis data set that is necessary to reproduce the research results in order to meet the moral and scientific obligation to enable verification of the research.

- A copy of the analysis data set will be shared with SHM. [NAME + CONTACT DETAILS] is the contact person for the analysis data set.

- The Institution is responsible for the proper reporting of the data analysis and the retention of the syntaxes/scripts written to carry out the analyses and obtain the research results.

- If a scientific journal requests the provision of the analysis data set, the Institution will request SHM’s consent for said provision and decide, together with SHM, in what form this provision of data can take place, while sufficiently safeguarding the privacy of Study participants whose Data are being shared.

- The Institution will provide SHM with a copy of all reports produced with these Data.

Signed at [PLACE], date [DATE]

[NAME OF INSTITUTION]

………………………….

[NAME + JOB TITLE]