NET-QUBIC Project
Data and biomaterial access policy

Procedure to receive data and/or biomaterials from the NET-QUBIC warehouse

Statements in the signed Research Agreement

According tot the signed NET-QUBIC research agreement, members of the NET-QUBIC Consortium (Annex I) are allowed to use the data stored in the NET-QUBIC Data Warehouse and Biobank, and write publications according to Annex IV "Publication policy" (Paper proposals, Co-authorship, and Data Access). Researchers from outside the NET-QUBIC Consortium can also use the data, but only in close collaboration with members of the NET-QUBIC Consortium.

As stated in Annex IV, Data stored in the Data Warehouse can be used by the Parties and Third Parties according to the following provided:

- To access the Data, a research proposal should be submitted in writing to the Principal Investigator according to Annex V (format for submitting a research proposal).
- After receiving a research proposal, the Steering Committee will discuss and decide on the use of the Data for the proposed study.
- If a Party decides not to participate, the Data from its institution will not be included in the proposed study.
- The Data can only be used for the proposed analyses, and is not allowed to be used for other studies nor should it be provided to Third Parties without written permission of the Steering Committee.
- In case other research questions are considered for which access to the Data is needed, approval by the Steering Committee of NET-QUBIC, for this new research question needs to be obtained.
- The Data are only available for non-commercial scientific research.
- For access to the Data a small amount of money is charged to compensate for the costs of data management. In case applicants are member of the NET-QUBIC Consortium, for patient-reported outcome measures an amount of €2,500 is charged and for biomaterials €5,000, provided that the retrieval of Data is within limits, in which case additional cost will be charged. In case of applicants who are not members of the NET-QUBIC Consortium these charges are €5,000 and €10,000, respectively. This charge does not apply to the four already approved PhD tracks.
- Recipients will have to sign the Data Sharing Agreement (Annex VII) before they receive the Data for analyses.

Access procedure for members of the NET-QUBIC Consortium

Abbreviations: PI: principal investigator, SC: Steering Committee

Procedure:

1) Research proposals can be submitted by members of the NET-QUBIC consortium listed in Annex I. Researchers from outside the NET-QUBIC consortium can also submit a research proposal but only in close collaboration with a member of the NET-QUBIC consortium. The proposals are always approved by the respective representative in the SC of a participating center before submitting the proposal (the local PI).
2) A research protocol is prepared. A format is attached (Annex V and VI). It contains Background, Research questions and preliminary work, Plan of investigation including statistical considerations, Budget, Financing and time schedule. Researchers should carefully read the information on the NET-QUBIC website to make sure that their research questions can be answered based on the available NET-QUBIC data. They can also contact the data release coordinator for questions, via data.netqubic@vumc.nl.
3) The protocol is sent to the NET-QUBIC PI Prof Verdonck-de Leeuw who will check whether the protocol overlaps with other running protocols and will forward it with an overview of possible overlap to the SC. The SC will judge the proposal on scientific merits as well as feasibility on basis of preliminary work and budget. The SC and PI keep all information confidential. The representatives in the SC consult the relevant parties within their centers, exchange comments and send an advice for participation to the NET-QUBIC PI within one month. Refusal by any center to share their data and biomaterials needs to be motivated as the intent of NET-QUBIC is to form a research infrastructure, supporting research. In case the proposal needs biomaterials and the advice of the steering committee is positive, the proposal will also be judged by the Biobank Committee of VUmc.
4) The comments of the SC are forwarded by the PI to the applicant and the SC representative of the respective center, with suggestions when relevant to improve the study design or add preliminary work.
5) When the advise is positive the study can start after signing the data sharing agreement (Annex VII of the research agreement)
6) Changes in the work plan will be communicated and evaluated by the SC.
7) The applicant sends a yearly progress report (1 A4) till publication of the data that will be evaluated by the SC.
8) Additional research data (for example new biomarkers) obtained from studies using NET-QUBIC data or samples are brought into the NET-QUBIC Data Warehouse for use in future studies without any charges.

Procedure for third parties outside the NET-QUBIC consortium

Third parties always seek collaboration with one of the consortium members, and follow the standard procedure. A maximum of two extra proposals with external partners is allowed per center, including only two proposals for PhD tracks.

Answers to specific scenarios that might occur

1) A proposal has been evaluated and is not approved by the SC for lack of preliminary work.
   The decision on the proposal is postponed with maximal 6 months.

2) Two comparable proposals are sent by two centers at the same time.
   The centers will seek collaboration and agree to a final proposal within a month. The agreements are described in the final proposal.

3) A center may send in two proposals or units of five when they are part of a PhD track (Annex IV) without any limit. Should there be a limit?
   There will be no limits for PhD tracks except for external collaborations (max 2).

4) A center may send in two proposals or units of five when they are part of a PhD track without any limit. (Annex IV). What if there are unforeseen circumstances during the process?
   Proposals can be withdrawn, but can subsequently be sent in by others.

5) A center wants to apply for a grant application and requires written access to the NET-QUBIC samples, and asks for a supporting letter.
   A proposal is sent to the NET-QUBIC PI, forwarded to the SC and is reviewed as indicated. Time constraints may cause complications.

Annex I Scientific members of the Consortium (revised)

Name	Affiliation	Specific tasks
Prof. dr. R.J. Baatenburg de Jong	Erasmus Medical Center, Rotterdam	Local PI (EMC)
Prof. dr. R.H. Brakenhoff	Amsterdam UMC	Biobank coordinator
Drs. W.W. Braunius	University Medical Centre Utrecht	
Prof. dr. R. de Bree	University Medical Centre Utrecht	Local PI (UMCU)
Dr. L.M. Buffart	Amsterdam UMC	
Dr. J. Buter	Amsterdam UMC	
Prof. dr. P. Cuijpers	Vrije Universiteit Amsterdam	
Dr. S.E.J. Eerenstein	Amsterdam UMC	
Dr. R.J.J. van Es	University Medical Centre Utrecht	
Dr. F. Lamers	Amsterdam UMC	Database coordinator
Dr. A. de Graeff	University Medical Centre Utrecht	
Dr. J.J. Hendrickx	Amsterdam UMC	
Prof Dr. C.M.L. van Herpen	Radboud University Medical Center, Nijmegen	
Prof. dr. E.R. van den Heuvel	University Medical Center Groningen Dept. of Epidemiology	
Dr. B.W. Lissenberg-Witte	Amsterdam UMC	
Dr. H. Jager- Wittenaar	University Medical Center Groningen	
Dr. F. Jansen	Amsterdam UMC	Data release coordinator
Dr. L.M. Janssen	University Medical Centre Utrecht	
Prof. dr. J.H.A.M. Kaanders	Radboud University Medical Center, Nijmegen	
Drs. L.H.A. Korsten	Amsterdam UMC	
Prof. dr. J.A. Langendijk	University Medical Center Groningen Dept. of Radiotherapy	Local PI (UMCG)
Prof. dr. B.F.A.M. van der Laan	University Medical Center Groningen	
Prof. dr. C.R. Leemans	Amsterdam UMC	Local PI (VUmc)
Prof. dr. M.A.W. Merkx	Radboud University Medical Center, Nijmegen	
Drs. D. Molenaar	Àmsterdam UMC	
Dr. E. Monninkhof	University Medical Centre Utrecht	
Drs. S.F. Oosting	University Medical Center Groningen Dept. of Medical Oncology	
Prof. dr. J.B. Prins	Dept. of Med. Psychology, Radboud University Medical Center, Nijmegen	
Dr. C.P.J. Raaijmakers	University Medical Centre Utrecht	
Prof. dr. J.L.N. Roodenburg	University Medical Center Groningen Dept. of Oral & Maxillofacial Surgery	
Prof. dr. J.P.J. Slaets	University Medical Center Groningen Dept. of Internal Medicine, Geriatric Medicine	
Prof. dr. B.J. Slotman	VU University Medical Center, Amsterdam	
Dr. C.M. Speksnijder	University Medical Centre Utrecht	
Prof. dr. R.P. Takes	Radboud University Medical Center, Nijmegen	Local PI (Radboud UMC)

Prof. dr. C.H.J. Terhaard	University Medical Centre Utrecht	Local PI (UMCU)
Dr. E.H. van der Meij	Medical Center Leeuwarden	
Dr. B. van der Vegt	University Medical Center Groningen Dept. of Pathology & Medical Biology	
Prof. dr. I.M. Verdonck- de Leeuw	Amsterdam UMC / Vrije Universiteit Amsterdam	Principal Investigator (PI)
Dr. M.R. Vergeer	Amsterdam UMC	
Dr. J. Voortman	Amsterdam UMC	
Dr. T.J. Warmerdam	Noordwest Ziekenhuisgroep, Alkmaar	
Dr. S.M. Willems	University Medical Center Groningen	

ANNEX IV to NETQUBIC Research Agreement

PUBLICATION POLICY (revised, including Data Access)

Paper proposals (presentations and all other publications)

- Paper proposals and any other publication including the written form of a presentation (such as a Powerpoint presentation), hereinafter collectively referred to as the Paper Proposal, should include information on authors, working title, the research question(s) to be addressed, the variables to be included, the analysis plan, the timetable and targeted journal(s) (see Annex V).
- The Principal Investigator will check potential overlap with other Paper Proposals or competing interests (i.e. ongoing studies using the Data Warehouse). In case of conflicts of interest that cannot be resolved by the individuals involved, the issues at hand will be presented in writing to the Steering Committee, which will make the final decision, blind to the involved authors.
- In case the proposed research activities and writing the Paper Proposal exceed the proposed timeline by six months or more, the topic will be made available to other researchers. Before exceeding the time line, the leading author may ask permission in writing of the Steering Committee to extend the proposed timeline.
- A leading (first) author can submit a maximum of two Paper Proposals at the same time. After a Paper Proposal has been submitted to a journal, the author is allowed to submit the next Paper Proposal. Paper Proposals for PhD students, i.e. proposals for papers to be part of the PhD thesis, are an exception. For a PhD thesis, a PhD proposal (Annex VI) can be submitted including a maximum of 5 papers answering several research questions.
- The review and finalized Paper Proposal will be submitted for publication in scientific peer-reviewed journals. The submitted version will be sent to all collaborators.
- Before submission, the Paper Proposal will be sent to the Steering Committee for information. The Steering Committee is entitled to comment on the publication within 30 days after receipt of the copy thereof.
- During the 30-day review period of a Proposed Paper referred to above, the Steering Committee shall be entitled to make a reasoned request that the Proposed Paper be delayed for a period of up to 90 days from the date of first submission to the Steering Committee in order to enable the Steering Committee to take steps to protect Confidential Information and/or Intellectual Property and the Party or Parties shall not unreasonably withhold its consent to such a request.
- The lead author (or corresponding author) is responsible for the quality of the paper.
- At the time of acceptance, the complete paper should be sent to the Steering Committee.
- When the Paper Proposal has been accepted for publication, the PDF of this paper will be e-mailed to each member of the NET-QUBIC Consortium or a link to the open access journal will be published on the NET-QUBIC website.

- Any Paper Proposal that is based (in whole or in part) on any Data will include an acknowledgement to the Funding Body, according to the Grant Regulations.

(Co-)Authorship

- The Principal Investigator and all Parties (local PIs and database, data release, and biobank coordinators (See Appendix I) that gave permission for the use of their Data will be actively approached by the lead author (or corresponding author) to participate as co-author in the proposed multicenter paper.
- For (co-)authorship, the Parties shall comply with the Vancouver Protocol, i.e. authorship credit should be based on (1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published.
- In all publications, the NET-QUBIC Consortium will be mentioned as a co-author, i.e. '(on behalf of) the NET-QUBIC Consortium.
- The following statement will be added as acknowledgement in each paper: "This study was carried out using the research infrastructure within the NET-QUBIC project sponsored by the Dutch Cancer Society/Alpe d'HuZes."

Data Access

Data stored in the Data Warehouse can be used by the Parties and Third Parties according to the following provided:

- To access the Data, a research proposal should be submitted in writing to the Principal Investigator according to Annex V.
- After receiving a research proposal, the Steering Committee will discuss and decide on the use of the Data for the proposed study.
- If a Party decides not to participate, the Data from its institution will not be included in the proposed study.
- The Data can only be used for the proposed analyses, and is not allowed to be used for other studies nor should it be provided to Third Parties without written permission of the Steering Committee.
- In case other research questions are considered for which access to the Data is needed, approval for this new research question needs to be obtained.
- The Data are only available for non-commercial scientific research.
- For access to the Data a small amount of money is charged to compensate for the costs of data management. In case applicants are member of the NET-QUBIC Consortium, for patient-reported outcome measures an amount of €2,500 is charged and for biomaterials €5,000, provided that the retrieval of Data is within limits. In case of applicants who are not members of the NET-QUBIC Consortium these charges are at least €5,000 and €10,000, respectively. This charge does not apply to the four already approved PhD tracks. When additional costs for Data retrieval are foreseen by VUmc, VUmc will inform the Recipient Party of the total costs involved before signature of this Agreement.
- Recipients will have to sign the Data Sharing Agreement (Annex VII) before they receive the Data for analyses.

ANNEX V: Proposal data and sample access NET-QUBIC

Date of submission:

Date of approval:

1. Working title

2. Name and affiliation of first and senior lead author

3. Suggested co-author(s)

4. Email address for correspondence

5. Background and rationale (1 A4)

6. Preliminary work and research question(s) (1 A4)

7. Data and samples to be used (0.5 A4)

(outcomes, patient population, time points etc)

8. Plan of investigation and method of analyses (1-2 A4)

9. Budget and time schedule(1 A4)

10. Proposed journals

ANNEX VI: Proposal PhD thesis NET-QUBIC

Date of submission:

Date of approval:

1. Working title thesis

2. Name PhD candidate and affiliations

3. Names promoter(s), co-promoter(s) and affiliations

4. Background and rationale

5. Preliminary work and research questions (5)

6. Plan of Investigation and method of analyses

7. Data and samples to be used

8. Budget and time schedule

ANNEX VII DATA SHARING AGREEMENT [for use by the Parties and Third Parties]

Netherlands Quality of Life and Biomedical Cohort Studies_Head and Neck Cancer

BETWEEN:

ORGANIZATION, established at ADDRESS, represented by _____, in ___ capacity of _____hereinafter referred to as “Recipient Party”

and

Stichting VUmc, established at De Boelelaan 1117, 1081 HV, Amsterdam, The Netherlands, in this matter duly represented by……., in capacity of ….., hereinafter hereinafter referred to as VUmc.

hereinafter, jointly or individually, referred to as ”Parties” or ”Party”

WHEREAS:

- The Consortium conducts a research programme entitled “Netherlands Quality of Life and Biomedical Cohort Studies_Head and Neck Cancer” designed to describe the long-term course of Quality-of-Life in Head and Neck Cancer patients and their informal caregivers and to identify cancer-related, personal, genetic, biological, psychobehavioural, physical, lifestyle-related, and social determinants of Quality of Life, which is funded by the Dutch Cancer Society / Alpe d’HuZes Foundation (hereinafter referred to as the “Project”);
- VUmc is the coordinator of the Project on behalf of the Consortium;
- The Recipient Party wishes to use the Data to conduct non-commercial research
- VUmc has agreed to provide the Data to the Recipient Party on the terms and conditions of this Agreement.

IT IS HEREBY AGREED AS FOLLOWS

1. Definitions

“Agreement” means this agreement.

“Anonymous Data” means data that has been modified in such a way that the information concerning personal or material circumstances can be attributed to an identified or identifiable individual only with a disproportionate amount of time, expense and/or labour, with the effect that this data is to be seen as being anonymous in a legal sense.

“Consortium” means the consortium consisting of the following members: Stichting VUmc, Radboudumc Nijmegen, Universitair Medisch Centrum Groningen, Universitair Medisch Centrum Utrecht, recipients of the grant awarded by the Dutch Cancer Society and Alpe d’HuZes Foundation, and Erasmus Medisch Centrum, Noordwest Ziekenhuisgroep, and Medisch Centrum Leeuwarden.

“Data” means any and all data of the Parties related to head and neck cancer patients and their caregivers, and obtained in the course of the Project.

“Principal Investigator” means the main applicant of the Project, prof. dr. I.M. Verdonck-de Leeuw (VUmc).

“Recipient Party” means the Party receiving Data.

“Steering Committee” means the committee of members of the Consortium.

“Study” means the study the Recipient Party wishes to conduct and for which it needs the Data.

1. Data

All Data to be provided by VUmc are encoded data.

2. Access

2.1 To access the Data, the Recipient Party shall submit a request in writing, outlining the Study to the Principal Investigator. The Study shall contain a synopsis for the use of the Data (hereinafter referred to as the “Permitted Use”).

2.2 Requests for access to Data may be submitted at any time and will be considered in the order in which they are received.

2.3 Upon receiving the request, the Steering Committee shall decide whether or not to grant access of the Data to the Recipient Party.

2.4 For access to the Data a small amount of money is charged to compensate for the costs of data management. For patient-reported outcome measures an amount of €2,500 is charged and for biomaterials €5,000, provided that the retrieval of Data is within limits. When additional costs for Data retrieval are foreseen by VUmc, VUmc will inform the Recipient Party of the total costs involved before signature of this Agreement.

2.5 Biomaterials which can, now or in the future, provide knowledge on the genetic profile of participants are not allowed to be transferred to the United States.

3. Obligations of the Recipient Party

3.1 The Recipient Party agrees that the Data will solely be used by the Recipient for the Permitted Use.

3.2 The Recipient Party will not provide or otherwise make available the Data to any third party or allow use of the Data by or on behalf of any third party, in whole or in part, whether by way of sale, resale, loan, transfer, hire or any other form of exploitation, not will the Recipient make the Data available online, in whole or in part, via the internet or intranet, or otherwise disclose the Data. The data will thus not be placed in an open online repository. When a scientific journal asks for open data, the following statement should be provided: Full dataset and statistical code is available via the NET-QUBIC consortium (PI prof. dr I.M. Verdonck-de Leeuw)”.

3.3 The Recipient Party will not link the Data with any other data set except as agreed in writing with the Steering Committee for the purposes of the Permitted Use.

3.4 The Recipient Party will not attempt to identify any individual from the Data provided.

3.5 Should the Recipient Party identify any individual from the Data, the Recipient Party will neither record this fact nor share the identification of that individual with any other person, nor will the Recipient attempt to contact the individual themselves.

3.6 If the Recipient Party identifies any individual from the Data, he will inform the Principal Investigator as soon as reasonably practicable, giving reasonable detail of the circumstances under which this occurred.

3.7 The Recipient Party will be responsible for ensuring that it has the telecommunications and other equipment and software (including security and virus-

checking software), with appropriate licences, necessary in order safely and securely to receive, access and use the Data for the Permitted Use.

3.8 The Recipient Party will restrict access to the Data to its employees who strictly need to access to the Data for the Permitted Use, and will ensure that all such employees are informed of the confidential nature of the Data and the importance of processing it securely.

3.9 The Recipient Party shall ensure that its employees do not take the Data or any subset of the Data home to work on or access the Data from any mobile device, including, but not limited to, smart phones and tablets.

4. Warranties, Indemnification and Limitation of Liability

4.1 The Recipient Party recognizes that the Data provided by VUmc are “as is” without any warranty of satisfactory quality or fitness for use or any other warranty, express or implied, and the Recipient Party recognizes that VUmc does not guarantee the complete accuracy of any Data furnished. Accordingly, VUmc cannot and will not accept liability for any loss arising as a result of any reliance placed on the Data.

4.2 The Recipient Party shall be liable in respect of any loss, claims, damage or liability, including third party claims, of whatsoever kind or nature, which may arise out of or in connection with the use, handling, storage or disposal of the Data by the Recipient Party.

4.3 In no event shall VUmc be liable to the Recipient Party or any third party for any special, incidental, consequential, exemplary, punitive, direct or indirect damages including, without limitation, loss of goodwill, loss of profits or revenue, loss of savings, work stoppage or data loss arising out of or in any manner connected with this agreement.

5. Publications [THIRD PARTIES]

5.1 The Recipient Party shall be free to publish and present the results of the Study, according to the publication policy in Annex IV. Prior notice of any planned publication shall be made to the Principal Investigator 30 days before the publication. The Recipient Party acknowledges that any publication of the Study is subject to the consent of the Steering Committee, such consent not to be unreasonably withheld. If no objection is made within 30 days of the notice of publication, the publication is permitted.

5.2 Authorship of all publications of the results of the Study shall include the names of senior researchers, to be provided by the Principal Investigator, from the Consortium involved in the Project.

5.3 The Recipient Party shall ensure that any publication or presentation that is based (in whole or in part) on any Data will include acknowledgement to the Dutch Cancer Society and the Alpe d’HuZes Foundation, to be provided by VUmc.

5. Publications [Consortium]

5.1 The Recipient Party shall be free to publish and present the results of the Study, according to the publication policy in Annex IV.

5.2 Authorship of all publications of the results of the Study shall include the names of senior researchers, to be provided by the Principal Investigator, from the Consortium involved in the Project.

5.3 The Recipient Party shall ensure that any publication or presentation that is based (in whole or in part) on any Data will include acknowledgement to the Dutch Cancer Society and the Alpe d’HuZes Foundation, to be provided by VUmc.

6. Intellectual Property

6.1 All intellectual property rights in the Data are and shall remain at all times the property of the members of the Consortium.

6.2 All results of the Study and all data and information generated in undertaking the Study are to be owned jointly by the members of the Consortium and the Recipient Party, (hereinafter “Joint Property”).

6.3 The members of the Consortium and the Recipient Party are responsible for the maintenance of the Joint Property and shall make additional arrangements thereto during the course of the Study. However, none of the members of the Consortium nor the Recipient Party shall license or otherwise commercialize the Joint Property without the written permission of the others nor without an agreement to be negotiated in good faith, providing for, inter alia, the sharing of income from the commercial exploitation of the Joint Property.

7. Term and Termination

7.1 This Agreement shall commence on [DATE] and shall continue until terminated in accordance with its terms.

7.2 This Agreement may be terminated by a Party with regard to itself by giving reasonable prior notice of such termination of not less than 30 working days to the other Party.

7.3 If a Party breaches any term or material condition of this Agreement and fails to remedy such breach, if capable of remedy, within thirty days after receipt of a written notice from the other Party specifying the non-compliance and requiring its remedy, or if a Party enters into bankruptcy or liquidation, the other Party may terminate this Agreement by serving notice of such termination, and such termination shall be effective as of the date of receipt of such notice by the breaching Party.

7.4 In the case of termination, the Recipient Party shall cease to use, and shall, at VUmc’s discretion, promptly return or destroy the Data supplied to it together with all copies thereof in its possession, and certify to VUmc that this has been done.

8. Law and Jurisdiction

8.1 This Agreement is governed by Dutch law. In case of international collaboration, the Recipient Party needs to abide to both the Dutch law and regulations as well as the laws and regulations of the Recipient Party.

8.2 The courts of Amsterdam shall have exclusive jurisdiction in relation to any dispute concerning this agreement

9. General

9.1 This Agreement may be modified and amended in writing by mutual consent of the Parties.

9.2 If any part or any clause of this Agreement proves to any extent invalid or unenforceable in law, the remainder of such clause and all other clauses of this Agreement shall remain valid and enforceable to the fullest extent permissible by law, and such clause shall be deemed to be omitted from this Agreement to the extent of such invalidity or unenforceability.

9.3 The terms of this Agreement that by their nature should survive the termination of this Agreement shall so survive, including without limitation, clauses 3, 4, 6, 7.4, and 8.

Agreed and signed in two copies,

_____	_____
(signature)	(signature)
_____	_____
(name and function)	(name and function)
_____	_____
(date)	(date)

Annex VIII

MATERIAL AND DATA TRANSFER AGREEMENT
NET-QUBIC

THE UNDERSIGNED:

1. **VU University medical center**, legally part of Stichting VUmc, a legal entity established under the laws of the Netherlands having its registered office at De Boelelaan 1105, 1081 HV, Amsterdam, Department of Otolaryngology- Head & Neck Surgery, Amsterdam, hereafter referred to as **"Provider",** for this matter legally represented by Anne Zijtregtop, managing director;

   and

2. **PARTY** having its office at ADDRESS, legally represented by TITLE, NAME, hereinafter referred to as "Recipient";

The foregoing (legal) entities are solely referred to as "Party" and collectively referred to as "Parties".

WHEREAS:

- The Provider has human biological material and related coded personal data available, which has been obtained on the basis of informed consent by the donor;
- The Material and Data (as described below) are generated under the Net-Qubic research agreement with the effective date of 1 May 2013 , which has been extended as of 1 May 2018 (''Research Agreement'') to which Provider and Recipient are a party, and is made and kept available at the VUmc Biobank, as a service to the research community for the purpose of the Net-Qubic project only;
- The Recipient is interested in conducting research with the Material and Data and has submitted a proposal for the Research to the Steering Committee of Net-Qubic (as provided for in the Research Agreement);
- The Steering Committee has approved the Research, which includes approval for the use of the Material and Data by the institution under which responsibility such Material and Data were generated
- The VUmc Biobank Research Ethics Committee has approved the release of the Material from the VUmc Biobank;
- The Provider is willing to provide the Material and Data to the Recipient, under the conditions set out in this agreement;

ARTICLE 1. DEFINITIONS

1.1 Provider: Organization providing the Original Material: VU University medical center

1.2 Provider Scientist: NAME, TITLE, DEPARTMENT

1.3 Recipient: Organization receiving the original material: NAME ADDRESS

1.4 Recipient Scientist: NAME, TITLE, DEPARTMENT

1.5 Original Material: Description of the material such as fractions from blood, oral rinses or biopsies collected for or part of the Net-Qubic study, as provided by Provider and specified in Appendix 1.

1.6 Material: Original Material, Progeny and Unmodified Deratives. The Material shall not include a) Modifications or b) other substances created by the Recipient through use of the Material which are not Modifications, Progeny or Unmodified Deratives.

1.7 Data: coded information concerning a Subject (Subject is a patient or other person) from whom the Material was taken, as defined in article 4 section (1) of the General Data Protection Regulation (EU) 2016/679, as well as clinical and pathological characterization of the Subject who provided the human material, transferred in a coded form from Provider to Recipient under this Agreement, collected under the Net-Qubic project, to be provided together with the Material, but only in pseudo-anonymized form and as specified in Appendix 1. The information provided does not allow direct identification of the Subject.

1.8 Progeny: Unmodified descendant from the Material, such as virus from virus, cell from cell, or organism from organism.

1.9 Unmodified Derivatives: Substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the Material. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the Material, proteins expressed by DNA/RNA supplied by the Provider.

1.10 Modifications: Substances created by the Recipient which contain/incorporate the Material which are not Unmodified Derivatives.

1.11 Non-commercial Purposes: The sale, lease, license, or other transfer of the Material or Modifications and/or Data to a non-profit organization for the Research only. Non-commercial Purposes shall also include uses of the Material and/or Data by any other profit or non-profit organization, including Recipient, to screen or analyse the Material and/or Data as part of joint conduct of the Research of which the results are made public.

1.12 Research: Recipient's research project in which the Material and Data will be used, as described in Appendix 1.

1.13 Results: the results from the Research.

ARTICLE 2. OWNERSHIP

2.1 Provider is willing to provide Recipient with the Material and the Data. As the Material is human material and the Data is human data, these are not owned by either Party, although Provider is custodian of the Material and the Data. Neither Recipient nor the scientists employed by the Recipient, nor any other third party shall have rights in the Material and/or Data other than as provided for in this Agreement.

2.2. The Material and Data shall be provided in quantities and allotments necessary for and during the study period of the Research and will be used by RECIPIENT for the purpose of the Research solely.

2.3. The costs for the Material, such as custom's clearance, transportation (as announced by the Steering Committee in accordance with article 11) are payable by RECIPIENT.

ARTICLE 3. USE

3.1 The Recipient agrees that:
(a) the Material and Data is to be used solely for Non –Commercial purposes
(b) the Material and Data is to be used solely for the Research described in the Research Protocol that is attached as Appendix 1 to this agreement;
(c) the Material and Data will not be used in human subjects, for contract research or for *in vivo* diagnostic purposes involving human subjects;
(d) the Material and Data is to be stored and used only at the Recipient´s organization and only in the Recipient Scientist's laboratory under the direction of the Recipient Scientist or others working under his/her direct supervision;
(e) the Material and Data will not be transferred to anyone else within or outside the Recipient organization;
(f) The Material and Data will be stored and used in compliance with the Research Protocol, other internal regulations from Provider applicable to providing material and all applicable statutes and regulations.

3.2 Without prior written consent from the Provider, the Recipient is not allowed to use the Material and/or Data in any other way than as stated under clause 3.1 a-f.

3.3 As an exception to article 3.1 under (d), Recipient is entitled to transfer Material and/or Data to collaborators as described in Appendix 1 to screen or analyse the Material and/or Data or to jointly conduct scientific research activities.

In such an event, Recipient will ensure and warrant to Provider that it will conclude an agreement with such collaborator in which they agree to the same terms and condition of this original MTA and as such the Collaborator will use the Material solely for the purpose of the Research and under the direction of the Recipient and not to use that Material for any other purpose without the express written consent of Provider. In all cases, Recipient and

Recipient scientist remain responsible for the Material and will ensure that any remaining material is transferred back to Recipient or destroyed. In the event Recipient wishes to transfer the material to other collaborators than described in Appendix 1, Recipient requires the prior written consent of Provider.

3.4 The Material and/or Data and/or any confidential information concerning the Material and/or Data will not be further distributed to others outside the Net-Qubic consortium without prior written permission from the institution under which responsibility the Material and Data were generated. If Recipient wishes to use the Material and Data for a certain Research other than described in Appendix 1, Recipient will refer such request to the Steering Committee, following the procedure regarding proposals for a (new) research project as described in the Research Agreement.

3.5 Recipient shall make no attempt to link or be able to link the Data to other databases or to process the Data in any way that it becomes Personal Data (again). In the event the Recipient, for whatever reason, identifies a Subject, it shall agree to preserve, at all times, the confidentiality of information relating to such Subject.

3.6 Any publication about the Data or the Material shall be subject to the publication provisions as set out in the Research Agreement.

ARTICLE 4. RESULTS

4.1 Results (as defined in the Research Agreement) generated with the Material and/or Data from work carried out as part of the Project shall be considered Research Results (as defined in the Research Agreement) and therefore shall be subject to the provisions of ownership as set out in the Net-Qubic Research Agreement.

ARTICLE 5 REPRESENTATIONS, WARRANTIES and LIABILITIES

5.1 Any Material delivered pursuant to this Agreement is supplied “as is” and is understood to be experimental in nature and may have hazardous properties. The Provider makes no representations and extends no warranties of any kind, either expressed or implied with regard to the Material or Data. There are no express or implied warranties or fitness for a particular purpose, or that the use of the Material and/or Data will not infringe any patent, copyright, trademark or other proprietary rights. The Provider agrees to promptly inform Recipient in writing if Provider obtains knowledge of any patent or property rights of third being infringed by the use of the Material.

5.3 Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage or disposal of the Material and Data, unless caused by gross negligence or willful misconduct of Provider. The Provider will not be liable to the Recipient

for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Material or Data by the Recipient, except to the extent prescribed by law when caused by the gross negligence or willful misconduct of the Provider.

ARTICLE 6. PUBLICATION

6.1. Publication of Results will be performed in accordance with the arrangements as included in the Research Agreement.

ARTICLE 7. CONFIDENTIALITY

7.1 Recipient agrees to keep confidential any proprietary information, know-how, data, or procedure related to the Materials and Data disclosed by Provider to Recipient under this Agreement ("Confidential Information"). Recipient agrees not to disclose Confidential Information to third parties. 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. These confidentiality obligations shall survive this Agreement for a period of five (5) years after termination or expiration of this Agreement. Any personal patient data or data suitable for identity disclosure contained in or related to the Material and Data have to be kept confidential by Recipient indefinitely.

7.2 The Parties acknowledge that the Data consists of coded data and that the Material is coded material of Subjects. Both are collected and maintained in accordance with the provided informed consent (ICF) and the applicable rules and legislation including but not limited to protection of privacy aspects of the medical and personal data and material of the persons. Provider warrants that the Material was legally acquired, and that the transfer to Recipient for the intended scientific research is legally allowed. Provider is not aware of any defects in the Material or of any other circumstances that would limit the intended use and value of the Material to Recipient under this Agreement. The Material will be coded and supplied when appropriate with basic Subject information. Under no circumstances shall the Provider supply personal information which could identify the Subject. The Recipient shall not carry out any procedures with the coded Data (linking, comparison, processing) with which the identity of the Subject could be derived.

7.3 In case of theft or loss of the material, Provider must be informed within 24 hours. In case of a data breach of data suitable for identity disclosure, Provider must be informed also within 24 hours.

ARTICLE 8. MISCELLANEOUS

8.1 The parties acknowledge that the patients from which Material derives or its representatives shall at all times have the right to request to destroy their Material, if the patients' Material has not yet been de-identified. In the event a patient files such a request with Provider (or at the institution where the person is a patient, after which the Provider is informed of this), the Recipient shall, if reasonably possible, promptly return the Material to Provider upon Provider's first written request or shall destroy the Material in an approved manner. A written confirmation of the destruction of the Material needs to be send to Provider. The Results already obtained through Research can be kept. With regard to Coded Personal Data which constitutes personal data, Recipient shall, upon Provider's first request, undertake to no longer use personal data for future research of individuals who have notified Provider (or the institution as meant in the above) that they no longer wish for their personal data to be processed or who have requested for erasure of their data and, to the extent legally required, Recipient will erase the data concerned.

8.2 The Parties further acknowledge that in case of a finding, (an unsought and unsuspected result of the research which is considered of immediate importance for the future health of an individual patient from which the Material was derived or its family)), Recipient will provide all relevant information to the Provider to allow Provider (or the institution as mentioned in article 8.1) to inform the patient.

8.3 Recipient will comply in all material aspects with all applicable laws and regulations such as, for example, those relating to research involving the use of patient material and/or data. Specifically, Recipient shall comply with Dutch health information security regulations (NEN7510 or IS027001/2) and, where applicable, the laws on the processing of personal data, with the General Data Protection Regulation (EU) 2016/679 applying from 25 May 2018.

8.4 In case a matter arises that is not foreseen in this agreement or in the Research Agreement, the Parties will refer the matter to the Steering Committee to provide a binding decision.

ARTICLE 9. EFFECTIVE DATE AND TERMINATION

9.1 This Agreement will become effective on [date] and shall terminate as described in article 3.2.

9.2 This Agreement will terminate on the earliest of the following dates: (a) on completion of the Research or (b) after three (3) years from the Effective Date.

9.3 Provider may terminate this agreement with immediate effect:

- if Recipient is in breach of this Agreement (including its Appendixes) and, in case a remedy is possible, fails to remedy such breach within a reasonable time after receipt of request by Provider to remedy such breach;
- in the event Recipient is in state of bankruptcy or suspension of payment or a petition to that effect is filed by or against that Recipient;
- in the event the business of the other Party will be winded up or closed down;
- in the event the control of the business of Recipient will be transferred to a third party;
- in the event the behavior of Recipient or its employees endangers the integrity of Provider in any way.

9.4. At all times Provider retains the right to recall the Material and/or Data on the following grounds:

- The Recipient or scientists employed by the Recipient fail to comply with the conditions of this Agreement and – in cases where remedy is possible, having been notified by Provider of this failure to comply - have not remedied such failure within a reasonable time after receipt of notification from Provider;
- the Subject or the Subject's representative withdraw its consent to or objects to the use of the Material and/or Data in research.

9.5 Upon the effective date of termination or expiry, Recipient will discontinue its use of the Material and/or Data and will, upon clear instructions from Provider, return or destroy, any remaining Material and Data. A written confirmation of the action taken is required.

9.6. If one Party is in breach of this agreement, this Party will be liable for any costs that may result from this breach.

9.7 The rights and obligations under this Agreement that by their nature would be expected to survive termination of this Agreement shall survive termination.

ARTICLE 10. GOVERNING LAW AND COMPETENT COURT

10.1 This agreement shall be interpreted, governed and enforced exclusively in accordance with the laws of The Netherlands.

10.2 All disputes between the Parties related to this Agreement, are to be instituted by the competent court of Amsterdam, The Netherlands.

ARTICLE 11. DETAILS PROVIDER AND RECIPIENT AND PROVISION OF DATA AND MATERIAL

11.1 The Material and Data is provided against the costs as announced by the Steering Committee which include material and/or data management costs and, if applicable, reconstruction costs and/or a handling and transmittal fee to reimburse the Provider for its preparation and distribution costs.

11.2 The Recipient will receive an invoice of the costs involved and will transfer the amount specified within 30 days of receiving the invoice to the Provider.

11.3 The transporter that Provider uses states that all the applicable licenses and required permits to transport human material in and outside the Netherlands are obtained. Provider cannot be held liable for any costs, damages or fines that may incur because of the absence of necessary licenses and/or permits.

11.4 The Provider will not be accountable or responsible for (change in) the quality of the human material during transportation.

*** signatures on next page

Agreed and signed in duplicate,

Provider	**Recipient**
_____	_____
Name:	Name:
Title:	Title:
Date:	Date:
READ AND ACKNOWLEDGED	READ AND ACKNOWLEDGED
Provider Scientist	**Recipient Scientist**
_____	_____
Name:	Name:
Date:	Date:

Appendix 1 – Research Protocol (description of the Research)