Re : Provision of data from the program *AURORA, Aiming to understand the molecular aberrations in metastatic breast cancer* ("AURORA Program"; "Study")

Dear Investigator,

This letter outlines the terms under which we agree to provide Program Data to you through your Institution. This letter creates a legal agreement between BIG, 20, Rue de Bretagne / Bretagnestraat, 1200 Brussels, Belgium ("BIG") and your Institution, [name and address] (the "Agreement"). BIG is the sponsor of the AURORA Program.

A detailed listing of the specific Program Data variables your Institute will be receiving will be agreed upon and finalized after signing this agreement.

The Program Data shall only be used by you in the context of your Research Project regarding the following:

[*full name of the Research Project*] ("Research Project")

This transfer of Program Data for this specific Research Project has been approved by the AURORA Program Steering Committee. Your Institution hereby confirms that you and/or your Institution has/have the appropriate funding to carry out the Research Project as defined above.

The Program Data are stored by BIG and are provided under the following conditions. They are being delivered in trust to your Institution for the Research Project's purposes defined above.

You and your Institution shall hold and maintain, and shall ensure that all employees, agents or independent consultants at all times hold and maintain in confidence all Program Data not in the public domain (or Program Data which entered the public domain pursuant to disclosure in violation of this Agreement) disclosed or provided or made available directly or indirectly by BIG, as applicable.

If requested by BIG, i) upon termination of your Research Project and /or ii) in case of termination of this Agreement by BIG due to a breach of the Agreement by you or your Institution, your Institution shall destroy all Program Data provided to you within the framework of this Agreement in your or your Institution's possession. Notwithstanding the foregoing, in case of i) above, you and your Institution shall be entitled to retain one (1) copy of Program Data for the sole purpose of transferring the Program Data to a data sharing platform in accordance with the provisions of this Agreement, if applicable.

You and your Institution shall comply with the obligations regarding the deletion of Personal Data in accordance with the Appendix IV to this Agreement.

The Program Data may not be sold, assigned or transferred to any other party, other than i) assignment and/or transfer to researchers at your Institution working with you on the Research Project, and/or ii) transfers to a data sharing platform for the only purpose of replicating and verifying the analyses performed in a Publication linked to the Research Project, subject to prior

written approval by BIG. In case of the ii) above, you and your Institution shall ensure that the transfer of Program Data shall be allowed only to a data sharing platform guaranteeing data access control. Such access to Program Data shall be detailed in a separate agreement (data transfer agreement or other relevant agreement) which shall be signed between the respective data sharing platform and the Program Data recipient, prior any transfer of Program Data taking place. The Institution shall ensure under such separate agreement that that the Program Data may only be used for the purposes of replicating and verifying the analyses performed in a Publication linked to the Research Project, and that such agreement shall contain the relevant data protection clauses required for compliance with Data Protection Laws. The Program Data may not be used for any other purpose than as described hereunder without the express prior written consent of BIG, subject to approval of the new purpose by the AURORA Program Steering Committee. Your Institution and you shall assume all responsibility for the safe use and handling, in compliance with this Agreement and all applicable laws, of the Program Data by you and your Institution's employees, agents and independent consultants after the Program Data have been provided to your Institution by BIG. BIG is not responsible or liable for any claims arising from your Institution's acceptance and/or your use of these Program Data.

The use of Program Data must be restricted to research experimentation in compliance with this Agreement and all international and national applicable laws and regulations including without limitation the Declaration of the Helsinki World Medical Association Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects including amendments thereto, the "ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice" and the "Notes for Guidance on Good Clinical Practice" CPMP/ICH/135/95, and the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679 repealing Directive 95/46/EC).

It is recognized and understood that certain existing inventions and technologies ("Background Intellectual Property") which are the separate property of your Institution and/or yourself and which are not affected by this Research Project shall remain your Institution's and/or your property.

For the avoidance of doubt, your Institution agrees that you are not acquiring any rights, title, or interest whatsoever in respect of the Program Data at all times, except for the limited use as agreed upon in this Agreement.

You are hereby through your Institution granted a right to use the Program Data solely for the purposes of carrying out the Project Research, subject to the terms of this Agreement.

The intellectual property rights on the Inventions generated within the framework of the Research Project shall be defined as per the Intellectual Property Rights Principles defined in Appendix I. Your Institution agrees, and you acknowledge and agree, to abide by these rules and principles.

Your Institution agrees and you acknowledge that all publications based on the use of the Program Data shall follow latest version of the Publication and Presentation Policy developed for the Study and attached as Appendix II of this Agreement.

In accordance with the Appendix III to this Agreement ("Policy for Access to Study Data and Biological Samples"), and the definitions therein, any data generated from the RP (such as assay results, a score based on a data analysis, etc.) must be made available with Study participant ID

(preferred option; this is the number allocated to the Study participant in the original Study) or with sample ID if participant ID was not shared with you and/or your Institution for potential future use in other RP (with appropriate acknowledgment of the RP researcher having generated such data). You are responsible to provide the data availability on a patient level (i.e. a list of available data) to BIG headquarters (HQ) within one (1) month of the publication of the RP.

You will be asked if you are willing to contribute to the new RP. If interested, and conditional on your contribution to the conduct of the RP and its associated publication or presentation, authorship may be considered.

Any request for access to and use of data generated as a result of the RP must be submitted for approval as a new RP. For the avoidance of doubt and notwithstanding article C of Appendix I, Institution retains in any case the right to use the Results that it has generated (excluding the use of the Program Data itself) for any research purposes, without the need for a new approval.

In the event that the approved RP requests access to results of a former RP, a DTA between the entities of the former RP and the new RP should be signed for the transfer of the results of the former RP, in addition to the DTA/MTA signed for access to the SD and/or RP BS. Unlike the DTA/MTA signed for access to the SD and/or RP BS, the additional DTA between the two RP entities is not coordinated by the RPPA and should be coordinated by one of the two entities. The RPPA will send one email to both researchers to inform them accordingly.

For the avoidance of doubt, the Program Data are provided “as is”, without warranty of any kind as to for use for any particular purpose or any other warranty express or implied or statutory.

BIG makes no representation or warranty that the use of the Program Data shall not infringe any third party rights. For avoidance of doubt, it is your Institution’s obligation to ensure that the use of the Program Data shall not infringe any third party rights.

You and Your Institution herewith explicitly represent and warrant that the Research Project will be conducted in accordance with the applicable laws and regulations regarding the use of the Program Data. The Program Data disclosed or otherwise made available to you or your Institution will not include any code or information allowing direct identification of the AURORA Program participants (hereafter ‘Data Subjects’). Further, you and your Institution herewith represent and warrant that you will not undertake any actions to determine the identity or personal data of Data Subjects, or to get access to any code allowing identification of Data Subjects. The Parties agree to attach to this Agreement an Appendix IV, to the extent applicable.

To the extent authorized by laws, your Institution hereby agrees to defend, indemnify and hold harmless BIG, its affiliates and its trustees, officers, employees, trainees and appointees from and against any liability or claim arising from any use of the Program Data by you and/or your Institution. BIG shall not be liable for any use by you and/or your Institution of the Program Data, nor any loss, claim, damage, or liability of whatsoever kind or nature which may arise from or in connection with this Agreement or the use of the Program Data. In no event shall BIG be liable for indirect, special, punitive or consequential damages including but not limited to loss of use, loss of data and loss of profits or interruption of business.

BIG may terminate this Agreement immediately, upon written notice to you and your Institution, in the event you or your Institution are in breach of this Agreement.

The terms, provisions, representations, warranties and covenants contained in this Agreement that by their sense and context are intended to survive the performance thereof by the Parties hereunder shall so survive the completion of performance, expiration or termination of this Agreement.

Your Institution's acceptance of the terms identified above is acknowledged by the signature of the present Agreement. You must not use the Program Data until your Institution has taken all actions necessary to implement the policies and legal terms set forth above and accepted by your signature below.

This Agreement shall be governed and construed in accordance with laws of Belgium. The Parties shall endeavour, in good faith, to settle any and all disputes amicably. In the event of any dispute, difference, controversy or claim arising out of or in connection with this Agreement, the Parties shall first attempt to settle such dispute by consultations in at least two (2) minuted meetings on the subject, with permanent documentation of the context, content, and decisions resulting thereof.

If in application of this Section, the Parties concerned have not reached a settlement of such dispute at the expiration of sixty (60) days after the second meeting, the dispute shall be finally settled by the exclusive competent courts of Brussels, Belgium.

The documents enumerated hereafter are understood to form an integrated part of this Agreement:

Appendix I: Intellectual Property Rights

Appendix II: Publications and Presentations Policy for TR Researches

Appendix III: Policy for Access to Study Data and Biological Samples

Appendix IV: Data Privacy

The Parties agree that this Agreement shall become effective and binding as from the effective date of the present Agreement under the condition that all the Parties have signed the Agreement. The Parties expressly recognize the electronic signature to be a valid signature for this Agreement.

Sincerely,

For BIG,

Name: Theodora Goulioti, MD

Title: CEO

Date:

Signature:

For the Institution representing the Investigator,

Name:

Title:

Date:

Signature:

Acknowledged by Investigator:

Name:

Title:

Date:

Signature:

Appendix I

Intellectual Property Rights

Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer
The AURORA PROGRAM

POLICY ON INTELLECTUAL PROPERTY RIGHTS DERIVING FROM THE AURORA PROGRAM

Protocol Numbers:	BIG 14-01
Policy Version and Date:	Version 2.0 dated 30/Aug/2021

DEFINITIONS

"AURORA Sites" means BIG Sites and Independent Sites participating in the AURORA Program.

"AURORA Partners" means all BIG Groups, BIG Sites and Independent Sites participating in the AURORA Program and the Breast Cancer Research Foundation ("BCRF"), which has provided the majority of the funding for the AURORA;

"AURORA Policy for Access to Program (both clinical and genomic) Data and Biological Samples" means the policy developed by BIG and endorsed by the Steering Committee governing access to and use of Program Data and Biological Samples, as well as the role played by the Steering Committee in such access;

"Background" means property of any kind (e.g. experiments, results, tests, trials, data , techniques, Confidential Information and specifications, whether tangible or intangible and whether protectable or unprotectable) which is held by an AURORA Partner prior to its participation in the AURORA Program and which is needed for carrying out a Research Project or for a Foreground use;

"BIG Groups" means research associations or other legal entities with expertise in conducting and/or coordinating oncology clinical trials selected by BIG, whose duties are to provide scientific leadership and to perform some of the tasks for the Program in their respective countries or in conjunction with Sites affiliated with such BIG Groups;

"BIG Sites" means those Sites affiliated with BIG Groups for the purposes of the Program, whether they are contracting with the BIG Group or not;

"Biological Samples" means the samples (including but not limited to primary tumor tissue (FFPE), metastatic lesion tissue (both frozen and FFPE), whole blood, plasma and serum and derivatives) collected in performance of the Program from Program patients in accordance with the AURORA protocol, to be used to conduct the analyses defined in the AURORA protocol, and later according to the Program Policy for Access to (both clinical and genomic) Data and Biological Samples;

"Commercial Use" means the direct or indirect utilization of Foreground in further for-profit use, other than those covered by the Research Project, including any activity which is carried out directly or indirectly for for-profit purposes;

"Downstream Clinical Trial(s)" mean(s) any clinical research as defined in the European Directive 2001/20/EC on clinical trials or in the European Regulation n° 536/2014 on clinical trials, once applicable, conducted by one or more AURORA Partners in collaboration (or not) with (a) commercial entity(-ies) or (an) academic entity(-ies) using the Program Data and/or the Biological Samples as molecular screening information and enrolling AURORA patients;

"Foreground" means any Intellectual Property Right which is generated within a certain Research Project;

"Gross Royalties" means all consideration received from the licensing, assignment, or other commercialization by the owner(s) of the Intellectual Property, including any fees paid by the

licensee such as up-front license fees or maintenance fees. If the owner(s) receive(s) equity in a company in connection with commercializing the Intellectual Property, the equity will also be treated as Gross Royalties.

“Independent Sites” means the sites which are not affiliated to a BIG Group in the context of the Program;

“Intellectual Property Rights” or “IPR” means all worldwide rights, titles and interests in or relating to intellectual property, whether protected, created or arising under the applicable national, European and international laws, including: (i) all patents and applications, therefore, including all continuations, divisionals, and continuations-in-part thereof and patents issuing thereon, along with all reissues, reexaminations and extensions thereof; (ii) all copyrights and all mask work, database and design rights, whether or not registered or published, all registrations and recordations thereof, and all applications in connection therewith, along with all reversions, extensions and renewals thereof; (iii) trade secrets; and (iv) all other intellectual property rights of any kind anywhere in the world.

“Know How” means unpatented technical information, including without limitation, materials and information relating to inventions, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests, manufacturing processes, techniques and specifications, quality control data, analyses, reports and submissions

“Licensing Costs” means the IPR owner(s)’s out-of-pocket costs of prosecuting, registering, licensing, and enforcing rights in the Intellectual Property (including all legal or other third-party fees, filing fees and other costs).

“Net Royalties” means “Gross Royalties” less “Licensing Costs.”

“Program” means the scientific research program entitled AURORA;

“Program Data” means all data, in any form, collected regarding the patients recruited within the framework of the Program, whether reported in the electronic Case Report Forms (e-CRFs) and stored on a dedicated database or collected via the IT Platform, including data resulting from the analyses of the Biological Samples collected in the Program;

“Research Project(s)” means one or more research project(s) conducted outside the AURORA protocol using Program Data and/or Biological Samples as specifically allowed pursuant to, and in accordance with the conditions of the AURORA Policy for Access to Program Data and Biological Samples, as the case may be, including for example translational research studies. Such Research Project(s) are not described in the AURORA protocol and funding has not yet been defined at the signature date of the BIG Group/BIG Site Agreement;

“Results” means all information, data, findings, test results, discoveries, inventions, processes, methods, techniques, formulae, substances, specifications, studies, designs or improvements whatsoever (whether patentable or not) that are originated, conceived, derived, produced, discovered, invented or otherwise made in the course of or as a result of the performance of the Research Project.

“Steering Committee (SC)” means the group comprising scientific experts and others as relevant, with overall responsibility for the scientific integrity of the Program and that shall report to the BIG Executive Board. The Steering Committee shall have the attributions described in the Steering Committee Charter;

PRINCIPLES

1. All Program Data are owned by BIG. All Program Data are deemed Confidential Information of BIG. Access to Program Data for Research Projects shall be granted according to the AURORA Policy for Access to Program Data and Biological Samples.

2. Biological Samples are stored in an independent biorepository, under the custodianship of BIG on behalf of the Steering Committee, which is responsible for the governance of the Biological Samples. It is understood that the Aurora Site will remain the custodian if requested or required by national regulation and, in this case, the Aurora Site decides the final use of the Biological Samples at all times. Access to such Biological Samples for Research Projects shall be granted according to the AURORA Policy for Access to Program Data and Biological Samples.

3. AURORA Partner(s), academic (not being an AURORA Partner) or commercial entities requiring access to and use of the Program Data and/or Biological Samples for conducting a Research Project shall sign an appropriate agreement with BIG which shall include the detailed terms and conditions of such access and use, as well as the following provisions: (i) confidentiality; (ii) commitment to use the Program Data and/or Biological Samples solely for the purpose of conducting the Research Project as approved by the Steering Committee, (iii) the commitment not to transfer the Study Data and/or Biological Samples to any third-party (except as such third party transfer (e.g., to affiliate, contractor, agent, collaborator) is approved by the Steering Committee; (iv) for each related publication or presentation, acknowledgement of the AURORA Program conducted under BIG's umbrella and commitment to abide by the ICJME guidelines; (v) the Research Project shall be conducted in accordance with all applicable laws and regulations and relevant ethical requirements, and the Policy for Access to Study Data and Biological Samples.

BACKGROUND

Each AURORA Partner remains the sole owner of its Background and Know-How. To the extent necessary for the performance of a Research Project and to the extent this AURORA Partner is legally able to do so, such AURORA Partner hereby grants a fully paid, non-exclusive, non-transferable license to use its Background and/or Know-How for the purpose of carrying out a Research Project or Downstream Clinical Trial, but for no other purpose, to the AURORA Partners carrying out such Research Project.

FOREGROUND

A. <u>IT Platform</u>

For the purposes of the AURORA Program, BIG has developed an IT platform where part of the data generated by the AURORA Program shall be uploaded and stored for further access and use under the AURORA Steering Committee's governance. Such IT platform, as well as all related intellectual property rights, is owned by BIG.

B. <u>Molecular Advisory Board ('MAB') input</u>

The MAB set in place for the AURORA Program shall provide some additional annotations on the data uploaded on the IT platform. Such intellectual input is protected by copyright and shall be owned by BIG.

C. Research Projects

As a general principle:

1. All IPR generated by a Research Project shall be owned by the person or the entity(-ies) responsible for the conduct of the Research Project ("IPR Owner(s)").

   In such case, upon request by the AURORA Partner(s), the IPR Owner shall make the Research Project Results, excluding any potential inventions arising from the Research Project, available to the requesting AURORA Partner(s), who shall have the right to use such Research Project Results, excluding inventions, for further research purposes, without compensation to the IPR Owner.

   For each Research Project in which invention(s) are made, the IPR Owner (including their inventors) shall grant, trough the data or material transfer agreement, to BIG and BCRF, a perpetual, fully paid, non-exclusive, non-transferable, non-sublicensable worldwide right and license to IPR Owner(s) (including their inventors) rights, title and interests (if any) under the invention(s), to use such invention(s) for non-commercial purposes, internal uses, patient care and educational purposes.

2. BIG shall be notified in writing of any Intellectual Property Rights of potential commercial interest, within two (2) months of its conception or discovery, or as soon as reasonably practicable thereafter, and in no event later than the filing of any patent application or any copyright registration incorporating the intellectual property.

3. The Owner(s) of IPR of potential commercial interest shall use diligent efforts to commercialize or cause intellectual property to be commercialized. The IPR Owner(s) shall notify BIG in writing within thirty (30) calendar days of the IPR Owner(s)'s execution of any license or other agreement exploiting the intellectual property and shall provide BIG with a copy of such agreement.

   Should the Owner(s) of the IPR elect not to file, continue to prosecute, issue or maintain the patent or patent application, or not to file equivalents in a particular country to the patent or patent application, the Owner(s) of IPR shall give BIG written notice of such election promptly, and in any event, at least three (3) months prior to any date that action must be taken to avoid abandonment or lapse. At such time, BIG shall have the right to take over at its sole expense and option the filing, prosecution or maintenance of any such patent application or patent or equivalent, except in the situation where the Owner(s) of the IPR has / have elected not to proceed so as to avoid disclosure of a trade secret such as through publication of a patent application that would disclose the trade secret.

   Should BIG elect not to file continue to prosecute, issue or maintain the patent or patent application, or not to file equivalents in a particular country to the patent or patent application, as per the section above, BIG shall have the right to transfer to BCRF the right to take over at its sole expense and option the filing, prosecution or maintenance of any such patent application or patent or equivalent, except in the situation where BIG has elected not

to proceed so as to avoid disclosure of a trade secret such as through publication of a patent application that would disclose the trade secret.

If BIG or BCRF takes over the filing, prosecution or maintenance of a patent or patent application, the Owner(s) of the IPR shall assign all of its rights in the patent application or patent to BIG or BCRF, subject to the retention by the Owner(s) of the IPR of a non-exclusive, royalty-free worldwide license for its internal research purposes only, and the Owner(s) of the IPR shall have no further responsibility for the licensing of such patent. In case BCRF takes over filing prosecution or maintenance of a patent or patent application, BCRF shall grant to BIG a non-exclusive, royalty-free worldwide license for such patent or patent application for its research purposes only. In case BIG takes over filing prosecution or maintenance of a patent or patent application, BIG shall grant to BCRF a non-exclusive, royalty-free worldwide license for such patent or patent application for its research purposes only. Even though the Owner(s) of the IPR has / have elected not to file, prosecute or maintain a patent or patent application, it / they shall provide reasonable assistance to BIG or BCRF if BIG or BCRF files, prosecutes or maintains such patent or patent application and shall execute and cause its employees, agents or consultants to execute such documents as are reasonably necessary to vest ownership of such application or patent in BIG or BCRF (as appropriate), and for BIG or BCRF to file, continue prosecution or maintain such patent application or patent.

4. All Licensing Costs for the intellectual property shall be borne by the entity filing the patent.

5. Subject to the following paragraph, should the results of a Research Project lead to a Commercial Use and provided that IPR Owner(s) is/are not restricted from doing so by contractual commitments towards third party(-ies), a right to share in the Net Royalties derived by the IPR Owner(s) from the Commercial Use of the IPR, calculated as follows, shall be granted to BIG:
    - BIG shall receive annual payments of ten percent (10%) of all Net Royalties and shall have the right to share the Net Royalties in accordance with its contractual obligations and/or gentleman's agreements.

    - BIG shall receive payment of BIG's share for any calendar year not later than February 28 of the following calendar year.

    The IPR Owner(s) shall provide BIG with written support for the calculation of the Net Royalties for the calendar year, and BIG shall have the right to audit the books and records of the AURORA Partners conducting the Research Project in order to verify the Net Royalties calculation.

    Any BIG's share shall be reinvested by BIG in BIG's activities as defined per its statutes.

D. <u>Downstream Clinical Trials</u>

Access and use of Program Data and/or Biological Samples, as well as recruitment of patients participating in the Program (provided they have given their informed consent, is granted to the AURORA Partners and/or academic entity(-ies) and/or commercial entity(-ies) for the purposes of conducting a Downstream Clinical Trial as approved by the Steering Committee, based on the PRINCIPLES provisions developed above.

For sake of clarity, we distinguish:

1.1 The inventions, results or data generated by the conduct of the Downstream Clinical Trial (the "Downstream Clinical Trial Outcome");

- any invention, results or data generated within the framework of a Downstream Clinical Trial sponsored by a commercial entity using its proprietary molecule and directly related to such proprietary molecule shall belong to the commercial entity. Further details about IPR rules shall be defined in the agreement entered into with such commercial entity for the purposes of the Downstream Clinical Trial;
- any invention, results or data generated within the framework of a Downstream Clinical Trial sponsored by an academic entity using the proprietary molecule of a commercial entity within the framework of a collaborative agreement, and directly related to such proprietary molecule shall belong either to the academic sponsor or the commercial entity as per the terms of such collaborative agreement. Further details of the IPR rules shall be defined in the agreement entered into between such academic and commercial entities for the purposes of the Downstream Clinical Trial.

1.2 The inventions, results or data generated by the combination (comparison, validation, analysis, etc.) of the Downstream Clinical Trial Outcome with the Program Data;

- The same rules as the above for the Research Projects shall apply, mutatis mutandis, i.e.:

As a general principle:

1. All IPR generated within such context shall be owned by the person or the entity(-ies) responsible for the conduct of the Downstream Clinical Trial ("IPR Owner(s)").
   In such case, upon request by the AURORA Partner(s), the IPR Owner shall make the Downstream Clinical Trial Results, excluding any potential inventions arising from the Downstream Clinical Trial, available to the requesting AURORA Partner(s), who shall have the right to use such Downstream Clinical Trial Results, excluding inventions, for further research purposes, without compensation to the IPR Owner.

   For each Downstream Clinical Trial in which invention(s) are made, the IPR Owner (including their inventors) shall grant, trough the data or material transfer agreement, to BIG and BCRF, a perpetual, fully paid, non-exclusive, non-transferable, non-sublicensable worldwide right and license to IPR Owner(s) (including their inventors) rights, title and interests (if any) under the invention(s), to use such invention(s) for non-commercial purposes, internal uses, patient care and educational purposes.

2. BIG shall be notified in writing of any Intellectual Property Rights of potential commercial interest , within two (2) months of its conception or discovery, or as soon as reasonably practicable thereafter, and in no event later than the filing of any patent application or any copyright registration incorporating the intellectual property.

3. The owners of IPR of potential commercial interest shall use diligent efforts to commercialize or cause intellectual property to be commercialized. The IPR Owner(s) shall notify BIG in writing within thirty (30) calendar days of the IPR Owner(s)'s execution of any license or other agreement exploiting the intellectual property and shall provide BIG with a copy of such agreement.

Should the Owner(s) of the IPR elect not to file, continue to prosecute, issue or maintain the patent or patent application, or not to file equivalents in a particular country to the patent or patent application, the Owner(s) of IPR shall give BIG written notice of such election promptly, and in any event, at least three (3) months prior to any date that action must be taken to avoid abandonment or lapse.At such time, BIG shall have the right to take over at its sole expense and option the filing, prosecution or maintenance of any such patent application or patent or equivalent, except in the situation where the Owner(s) of the IPR has elected not to proceed so as to avoid disclosure of a trade secret such as through publication of a patent application that would disclose the trade secret.

Should BIG elect not to file continue to prosecute, issue or maintain the patent or patent application, or not to file equivalents in a particular country to the patent or patent application, as per the section above, BIG shall have the right to transfer to BCRF the right to take over at its sole expense and option the filing, prosecution or maintenance of any such patent application or patent or equivalent, except in the situation where BIG has elected not to proceed so as to avoid disclosure of a trade secret such as through publication of a patent application that would disclose the trade secret.

If BIG or BCRF takes over the filing, prosecution or maintenance of a patent or patent application, the Owner(s) of the IPR shall assign all of its rights in the patent application or patent to BIG or BCRF, subject to the retention by the Owner(s) of the IPR of a non-exclusive, royalty-free worldwide license for its internal research purposes only, and the Owner(s) of the IPR shall have no further responsibility for the licensing of such patent. In case BCRF takes over filing prosecution or maintenance of a patent or patent application, BCRF shall grant to BIG a non-exclusive, royalty-free worldwide license for such patent or patent application for its research purposes only. In case BIG takes over filing prosecution or maintenance of a patent or patent application, BIG shall grant to BCRF a non-exclusive, royalty-free worldwide license for such patent or patent application for its research purposes only. Even though the Owner(s) of the IPR has / have elected not to file, prosecute or maintain a patent or patent application, it shall provide reasonable assistance to BIG or BCRF if BIG or BCRF files, prosecutes or maintains such patent or patent application and shall execute and cause its employees, agents or consultants to execute such documents as are reasonably necessary to vest ownership of such application or patent in BIG or BCRF (as appropriate), and for BIG or BCRF to file, continue prosecution or maintain such patent application or patent.

4. All Licensing Costs for the intellectual property shall be borne by the entity filing the patent.

5. Subject to the following paragraph, should the results of a Downstream Clinical Trial lead to a Commercial Use and provided that IPR Owner(s) is/are not restricted from doing so by contractual commitments towards third party(-ies), a right to share in the Net Royalties derived by the IPR Owner(s) from the Commercial Use of the IPR, calculated as follows, shall be granted to BIG:
    - BIG shall receive annual payments of ten percent (10%) of all Net Royalties and shall have the right to share the Net Royalties in accordance with its contractual obligations and/or gentleman’s agreements.

    - BIG shall receive payment of BIG’s share for any calendar year not later than February 28 of the following calendar year.

The IPR Owner(s) shall provide BIG with written support for the calculation of the Net Royalties for the calendar year, and BIG shall have the right to audit the books and records of the AURORA Partners conducting the project in order to verify the Net Royalties calculation.

Any BIG's share shall be reinvested by BIG in BIG's activities as defined by its statutes.

Appendix II

Publications and Presentations Policy for TR Researches

Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer

The AURORA PROGRAM

Publications and Presentations Policy (Including Abstracts and Posters)

1. Introduction

The Breast International Group (BIG) is conducting a molecular screening program entitled "Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer" (the "Program" or "AURORA"), and this document outlines the Program's Publication and Presentation Policy.

The principles outlined in this document are based on the BIG publication guidelines and are in accordance with the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts submitted to Biomedical Journals, April 2010 (www.ICMJE.org).

The term "Publication" applies to full manuscripts and abstracts related to these manuscripts.

The term "Presentation" includes oral presentations, posters, or poster discussions, and their corresponding abstracts.

It is assumed that the Program shall have several Publications and Presentations and that a distinction shall
be made between those that are "Core" and those that are "Additional", as defined hereunder.

"Core" are those that report on the primary research questions i.e. on data subsets of the Program analysed by the AURORA Data Analysis Committee (DAC) set up for the Program. This includes Publications and Presentations by the DAC Core Group and by any of the DAC Working Groups. The DAC is composed of individuals with expertise in clinical oncology, genetics, genomics and bioinformatics. The Core Group will be conducting bioinformatic and/or statistical analyses on the AURORA study population as a whole. The Working Groups will be conducting the bioinformatic and/or statistical analyses for specific patient populations, or to answer specific research questions.

"Additional" are those that report on any other analyses approved by the AURORA Steering Committee (SC)i.e. analyses proposed and performed outside the DAC Core Group or the DAC Working Groups. This includes Publications and Presentations

• driven by investigators (Publications and Presentations by BIG Groups/individual institutions reporting on a subset of Program data related to patients from their sites)
• on Research Projects (RP)

All Publications and Presentations should be based on analyses that have used

- data from the Program specific central database – consisting of the clinical database managed by IJB-CTSU and the molecular screening IT platform managed by BIG - that use all relevant patients in the central Program database.
- data derived from the analysis of biological samples in accordance with the AURORA protocol and/or any data generated from any central analysis of the biological samples approved by the SC and/or
- any data generated by RPs approved by the AURORA SC.

2. Core Publications and Presentations

2.1 Governing Body

The AURORA Steering Committee (SC) is the body responsible for all issues related to the reporting of Program related data and results in the form of publications in scientific journals and presentations at conferences.

The SC shall endorse the writing committee (WC) assigned for each Publication and Presentation, and shall ensure that the Program constituencies are appropriately represented in this.

The composition of the WC may differ for each Publication and Presentation and should be kept small.

For each such Publication or Presentation the SC shall:

1. Designate the individual(s) who should lead the activities within each WC (i.e. the first author);
2. For Publications, approve authorship, including who should serve as first and last author. In general, the first author is responsible for the preparation of the first draft manuscript, circulation to and approval by co-authors, liaison with the journal/conference in which the Publication/Presentation should appear or be made, submission of the final approved Publication/Presentation to the journal/conference, collection and submission of conflict of interest forms from all the co-authors, follow upon on any questions related to the Publication, as well as making the Presentation and must therefore be member of the WC at hand;
3. For Presentations, approve the individual who is to make the Presentation, as well as the list of authors;
4. Resolve any disagreements within the WC about authorship.

The mandate of the WC shall be to:

1. Prepare a high quality Publication or Presentation on the topic/subject matter assigned to it;
2. Ensure that the Program Publications and Presentations Policy is applied to the Publication and/or Presentation that is being prepared.

Correspondence between the SC and the WC shall be by email with specified “respond by” dates.

The WC cannot make amendments to this Publications and Presentations Policy document without SC approval.

2.2. Publications and Presentations

- Proposals for specific analyses made by the DAC Working Groups will have a limited period of protected time (9-12 months) from the time of Program Data receipt, in which similar proposals from other investigators are rejected. If after this period no results have been shared with the SC by the DAC Working Group, a collaboration might be proposed between the DAC Working Group and the other investigators with a similar proposal.
- In the title of the Publications or Presentations it must be made clear that the Program is sponsored by BIG.
- Prior to submission to the journal/conference of a proposed Publication or Presentation, the first author shall share the final draft with the SC coordinator at BIG Headquarters (HQ) (aurora.bighq@bigagainstbc.org) for review by the SC.
- The SC shall review and approve the material to be published or presented within ten (10) working days for a Publication and five (5) working days for a Presentation.

2.3. Authorship, Acknowledgments and Presenters

Authorship should be based on the principle of respect for all partners, groups, investigators and countries/regions involved in the Program. Authorship credit should follow the ICMJE guidelines. In addition, the following recommendations to the WCs and SC are made:

- When allowed by a journal, authorship must be on behalf of the overall Program, publishing in the name of BIG and the groups and investigators involved in the SC, in the DAC Core Group or DAC Working Groups or otherwise participating;

- When individual authors are to be listed, the maximum number of author positions allowed by a journal should be filled;

- Prime authorship positions should be given to those who have provided the most scientific leadership (e.g., clinical, translational, bio-statistical expertise related to hypotheses, design, protocol writing, key scientific expertise) rather than those whose contributions have been more administrative (e.g. Program Management);

- Other author positions should be reserved for:

    - Collaborative groups, allotting authorship in proportion to their contribution to the Program. If allowed by the journal, groups should be named as groups, with individual representatives of groups mentioned in the acknowledgements;

    - The principal investigator at high recruiting sites, in order of recruitment numbers.

- Individuals involved in the conduct of the Program;

- The sponsor, being BIG;

- Any other partner not listed above, who has significantly contributed to the Program.

- Funding bodies must always be listed in the acknowledgment section of any Publication. BIG HQ shall provide a current list of those at any time, including the order in which they must be mentioned, and the grant identification number of the funding bodies, if applicable.

- Those who are not accorded an authorship position and have participated in the Program should appear in the acknowledgments. The number of acknowledgments per participating entity (i.e., partners, groups, investigators and countries/regions) depends on the journal's rules and be based on fair and practical considerations.

- Authorship should be rotated across Publications, e.g. no individual should appear as first author on consecutive Core Publications; constituencies (e.g., institutions) on consecutive Publications should be represented by different individuals who contributed significantly.

  If more than one individual would be appropriate to represent a particular constituency on a particular Publication/Presentation, but only one author position can be allocated, it should be the constituency's responsibility to make the selection

For oral Presentations, presenters are approved by the SC. In all cases, presenters should be rotated across Presentations.

3. Publication and Presentation by Groups/Individual Institutions

After the publication of the results of the analyses performed by the DAC Core Group or by any of the DAC Working Groups, groups/individual institutions shall be allowed to publish/present the data and results from their site(s), i.e. clinical data from the Program specific central database and TGS results from the molecular screening IT platform managed by BIG, provided the following conditions are met:

- The proposed Publication/Presentation is in line with the principles outlined in this document and first submitted to the Program SC as follows;

  - Prior to submission to the journal/conference of a proposed Publication or Presentation, the first author shall share the final draft with the SC coordinator at BIG HQ (aurora.bighq@bigagainstbc.org) for review by the SC
  - The SC shall review and approve the material to be published or presented within ten (10) working days for a Publication and five (5) working days for a Presentation.

- The Publication/Presentation is not made in the name of the Program, but properly acknowledges that the data collection was made possible through the Program and all the entities funding the Program (to be asked to BIG HQ at aurora.bighq@bigagainstbc.org) and a reference to BIG as the sponsor of the Program will be made.

4. Publications and Presentation on Research Projects

With regard to Presentations or Publications on Research Projects, approved by the SC, the following principles apply :

- Publications are expected to have a draft version circulated for review to the authors within 2 years of data transfer;
- They should not be presented or published prior to the first Core Publication of the main Program, unless otherwise agreed upon by the SC;
- They shall not use unpublished data;

- Researchers must inform BIG HQ of planned Publication/Presentation before submission to a journal/conference, for review as follows:

    - Two SC members who have been assigned to serve as link between the RP and SC, will review the proposed Publication or Presentation, on behalf of the SC. They will review and approve the material to be published/presented within ten (10) working days for a Publication and five (5) working days for a Presentation. Conditional on their contribution to the conduct of the RP and its associated Publication or Presentation, the designated SC members might have an authorship position.
    - In addition to the SC members assigned to a RP, the authorship for RP Publication or Presentation is defined by the RP team, as identified in the RP proposal form, to include and acknowledge those contributing to the RP. SC approval of the authorship as defined by the RP team is not required.

- All Publications and Presentations must acknowledge the Program as the source of the Program Data/RP Biological Samples used in the RP, and the Program partners (BIG, IJB-CTSU and Frontier Science), and all the entities funding the Program (to be asked to BIG HQ at aurora.bighq@bigagainstbc.org) and a reference to BIG as the sponsor of the Program will be made.

- Copies of all final manuscripts/abstracts arising from the RP which are accepted for Presentation or Publication must be sent to the SC (via BIG HQ) for information.

Appendix III

Policy for Access to Study Data and Biological Samples

AURORA

Policy for Access to Study Data and Biological Samples

Protocol Numbers:	BIG 14-01
Policy Version and Date:	Final version 2.0 – 22 Apr 2021

Table of Contents

1. List of abbreviations

BS	Biological Samples
DTA	Data Transfer Agreement
MTA	Material Transfer Agreement
RP	Research Project
RPP	Research Project Proposal
RPPA	Research Project Proposal Administrator
SC	Steering Committee
SD	Study Data
WD	Working Days

2. Introduction

In the AURORA study, study data (SD) and biological samples (BS) are collected from each of the study participants. Data and material are available for the purposes of the study as outlined in the protocol and the informed consent form, as well as for future research beyond the study by investigators and by the wider scientific community.

This policy does not cover for the use of SD and BS as defined in the study protocol, but applies to Research Project (RP)s beyond the protocol that require access to SD and/or RP BS collected or generated during the study.

RP BS are the BS that are available for RP and stored under the custodianship of BIG and the academic partners on behalf of the Steering Committee (SC) in a specialized biorepository that is independent from any of the study partners. The biorepository for AURORA is Integrated Biobank of Luxemburg (IBBL).

A formal, fair, and transparent scientific review process is necessary to ensure that SD and RP BS collected during the study are accessed appropriately. This policy describes the principles for RPs and the procedures for the submission, review and approval of RP using AURORA SD and/or RP BS. This policy has been approved by the Steering Committee (SC) of the AURORA study.

The term researcher used in this policy refers to any person, or legal entity which submits a RPP that needs to be approved by the SC, and receives the SD and/or RP BS in order to conduct its RP.

3. General principles

- ***Access to data***

Once the analysis related to a subset of data has been published, requests for access to SD (without BS) may be made at any time, with no deadline for submission set up front.

➢ *Access to biological samples*

The SC will periodically issue a "Call for Research Project Proposals". This call will be announced via various means, including but not limited to the BIG website and in study newsletters, and a deadline for submission will be specified.

➢ *Requirements for Research Project Proposal (RPP)s*

The RPPs will be assessed on the basis of their scientific merit, so they should clearly explain the scientific rationale, potential clinical impact and proposed method of analysis. In addition, they must:

- Specify exactly what types and amount of SD and/or RP BS are needed, based on the proposed analysis and the statistical rationale;
- Be self-funded;
- The researcher will need to foresee the payment of an access fee, to cover the cost of the management of the RPP, the preparation of the data sets, and the transfer of data/samples
- Comply with all applicable laws.

Informed Consent for use of RP BS and SD in RPs

RP BS and SD must only be used for the purposes defined in the RP, approved in accordance with the present Policy, provided that they are consistent with the study participant's consent obtained for the original study.

The evaluation of whether the RPP is covered by the study participant informed consent, or whether additional consent is required will be made by the Sponsor (BIG).

When the research use intended is inconsistent with or beyond the scope of the original consent, the project cannot be considered.

➢ *Review and approval of RPPs*

- All RPPs must follow the review and approval process as described in this policy.
- Before being submitted to the SC for approval,
    - o an assessment of clinical data and/or samples' derived data and/or samples availability will be made,
    - o a limited group of reviewers will perform an in-depth scientific review as follows:

- For Data only proposals (whether SD or data generated from a RP):

representatives of the central team (BIG Headquarters, bioinformatician and/or data transferring entity) will perform a feasibility review of the RPPs (incl. a check to ensure there is no overlap with previously approved proposals) and will decide if the individual RPP could be recommended to the SC for approval or if a more in-depth review is needed, with the rationale of this decision (recommendation or review) provided to the SC.

The SC chair(s) appoint(s) 2 (two) voting members of the SC to evaluate the RPPs requiring a more in-depth review.

- For RP requiring access to SD and RP BS:

the SC chairs appoint 3 (three) SC voting members with the appropriate expertise to evaluate the scientific aspects of all RPPs per call. A different set of evaluators will be assigned for each call.

- If similar RPs are submitted (redundant or overlapping objectives and equal scientific merit), the SC can encourage collaboration. In the cases where the SC encourages collaboration, but it is not possible, the decision on the RP to be approved is made upon vote of the SC.

➢ *Conflict of interest*

- If a RPP for accessing data is submitted by a representative of the central team, the basic scientific review step by the central team is not performed, and an in- depth review will be done by the 2 SC members appointed by the SC chairs.
- The SC member(s) will be excluded from the evaluation of any RP in which they, or individuals from their institution/organisation participate. In case of conflict, they will be replaced by a different SC member assigned by the SC chairs.

➢ *Agreements*

All approved RPPs must have a Materials Transfer and/or Data Transfer Agreement (MTA/DTA) before any transfer of SD and BS can occur.

Such MTA/DTA is signed by the researcher, BIG HQ and the data transferring entity (if other than BIG HQ) and includes the RPP information, clauses related to data ownership, Intellectual Property Rights (IPR), publication, confidentiality, and any other principles or procedures that may apply and the access fee. This agreement includes a subset of non-negotiable clauses, including. the following provisions:
(i) confidentiality; (ii) commitment to use the Program Data (as defined in the Appendix I) solely for the purpose of conducting the RP as approved by the SC, (iii) the commitment not to transfer the Program Data to any third-party (except as such third party transfer (e.g., to affiliate, contractor, agent, collaborator) is approved by the SC; (iv) for each related publication or presentation, acknowledgement of the AURORA study conducted under BIG's umbrella and commitment to abide by the ICJME guidelines; (v) the RP shall be conducted in accordance with all applicable laws and regulations and relevant ethical requirements, and this Policy.

Any invention generated within the framework of a RP shall be as per provisions of the Appendix I.

➢ *Execution of the RP*

All RPs must be performed as per the proposal approved by the SC. Two SC members will serve as an advisor to the researcher, and will follow the RP up to publication, to ensure that the RP is executed in accordance with the proposal approved by the SC.

Researchers are expected to provide regular updates to the assigned SC members (every 6 months after data transfer), and for data only RPs, have to report the initial results of their analysis to the AURORA SC within 1 year of data transfer.

In case of post-approval updates to the RP involving major changes in the objectives, endpoints or analysis plan, the revised RPP must undergo another review process and approval by the SC.

➢ *Publications and Presentations on RPs*

The following principles apply for all proposed abstracts, publications or presentations on RP that were approved by the SC:

- Publications are expected to have a draft version circulated for review to the authors within 2 years of data transfer;
- They should not be presented or published prior to the first Core Publication of the main Program, unless otherwise agreed upon by the SC;
- They shall not use unpublished data;

- Researchers must inform BIG HQ of planned Publication/Presentation before submission to a journal/conference, for review as follows:

    - Two SC members who have been assigned to serve as link between the RP and SC, will review the proposed Publication or Presentation, on behalf of the SC. They will review and approve the material to be published/presented within ten (10) working days for a Publication and five (5) working days for a Presentation. Conditional on their contribution to the conduct of the RP and its associated Publication or Presentation, the designated SC members might have an authorship position.
    - In addition to the SC members assigned to a RP, the authorship for RP Publication or Presentation is defined by the RP team, as identified in the RP proposal form, to include and acknowledge those contributing to the RP. SC approval of the authorship as defined by the RP team is not required.

- All Publications and Presentations must acknowledge the Program as the source of the Program Data/RP Biological Samples used in the RP, and the Program partners (BIG, IJB-CTSU and Frontier Science), and all the entities funding the Program (to be asked to BIG HQ at aurora.bighq@bigagainstbc.org) and a reference to BIG as the sponsor of the Program will be made.

- Copies of all final manuscripts/abstracts arising from the RP which are accepted for Presentation or Publication must be sent to the SC (via BIG HQ) for information.

➢ *Confidentiality*

The content of all RPPs must be kept confidential by all reviewers (central team, SC members).

Transfer of information, SD and/or RP BS to another party, not specified in the approved RP and the corresponding MTA/DTA is prohibited.

➢ *Left-over BS after the RP*

Any material from the requested RP BS that is left over after completion of the approved RP, must be returned to the study repository.

Any additional use of the left-over material beyond the initial RPP must be submitted for approval as a new RP following the processes described in this Policy.

- ***Data Generated as a result of the RP***

Ownership of the data resulting from a RP : please see Appendix I

Any data generated from the RP (such as assay results, a score based on a data analysis, etc.) must be made available with study participant ID (preferred option; this is the number allocated to the study participant in the original study) or with sample ID if participant ID was not shared with the researcher for potential future use in other RPs (with appropriate acknowledgment of the RP researcher having generated such data). The researcher is responsible to provide the data availability on a patient level (i.e. a list of available data) to BIG HQ within one month of the publication of the RP.

The researcher of the RP whose data will be used will be asked if he/she is willing to contribute to the new RP. If interested, and conditional on his/her contribution to the conduct of the RP and its associated publication or presentation, authorship may be considered.

Any request for access to and use of data generated as a result of the RP must be submitted for approval as a new RP.

In the event that the approved RP requests access to results of a former RP, a DTA between the entities of the former RP and the new RP should be signed for the transfer of the results of the former RP, in addition to the DTA/MTA signed for access to the SD and/or RP BS. Unlike the DTA/MTA signed for access to the SD and/or RP BS, the additional DTA between the two RP entities is not coordinated by the RPPA and should be coordinated by one of the two entities. The RPPA will send one email to both researchers to inform them accordingly.

4. Procedures from submission of RPPs until data/sample transfer

- Researchers must fill in the RPPS Form providing all required information and submit the proposal to the RPPA at BIG HQ, who will coordinate the review and approval process.
- Timelines for review

    - For RPPs requiring access to SD and RP BS, it is estimated that researcher will be informed about the SC decision 60-80 working days after the submission deadline. In case the requested data or RP BS are not available, the researcher will be informed about the rejection within 16-25 WD after the submission deadline.
    - For RPPs requiring access to SD only: RPPs will be reviewed latest on a quarterly basis

- The RPPA will inform the researcher about the SC decision: “Approve”, “Conditionally Approve” or “Reject”, including the rationale for the decision in case of rejection, or conditional approval.
- For projects that are “conditionally approved”, it is the responsibility of the researcher to ensure that the RPP is adapted according to the SC comments and provided via the RPPA to the SC, within six (6) months, for a final decision. If this period is exceeded the RPP will be rejected.
- Proposals that are “Rejected” may be re-submitted for a full review after suitably addressing the concerns and comments raised by the SC. The process will stop after the second rejection of the RP by the SC.
- For approved projects, the RPPA will coordinate the negotiation and sign-off of an MTA/DTA between BIG HQ, the Data transferring entity (if other than BIG HQ) and the researcher
- For approved projects using RP BS, the researcher has to confirm EC approval of the project
- Once the MTA/DTA is signed by all parties, the data and samples (if applicable) will be prepared for transfer to the researcher, within a time frame to be defined by the data and sample transferring entities, without unnecessary delays.
- In case the RP researcher has questions regarding the data or samples received (s)he will contact the respective data/sample transferring entity directly.

Appendix IV

Data Privacy

EUROPEAN COMMISSION

Brussels, 4.6.2021
C(2021) 3972 final ANNEX

ANNEX

to the

COMMISSION IMPLEMENTING DECISION

on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council

ANNEX

STANDARD CONTRACTUAL CLAUSES

SECTION I

Clause 1
Purpose and scope

a. The purpose of these standard contractual clauses is to ensure compliance with the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) for the transfer of personal data to a third country.
b. The Parties:
    i. the natural or legal person(s), public authority/ies, agency/ies or other body/ies (hereinafter "entity/ies") transferring the personal data, as listed in Annex I.A. (hereinafter each "data exporter"), and
    ii. the entity/ies in a third country receiving the personal data from the data exporter, directly or indirectly via another entity also Party to these Clauses, as listed in Annex I.A. (hereinafter each "data importer")

    have agreed to these standard contractual clauses (hereinafter: "Clauses").

c. These Clauses apply with respect to the transfer of personal data as specified in Annex I.B.
d. The Appendix to these Clauses containing the Annexes referred to therein forms an integral part of these Clauses.

Clause 2
Effect and invariability of the Clauses

a. These Clauses set out appropriate safeguards, including enforceable data subject rights and effective legal remedies, pursuant to Article 46(1) and Article 46 (2)(c) of Regulation (EU) 2016/679 and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679, provided they are not modified, except to select the appropriate Module(s) or to add or update information in the Appendix. This does not prevent the Parties from including the standard contractual clauses laid down in these Clauses in a wider contract and/or to add other clauses or additional safeguards, provided that they do not contradict, directly or indirectly, these Clauses or prejudice the fundamental rights or freedoms of data subjects.
b. These Clauses are without prejudice to obligations to which the data exporter is subject by virtue of Regulation (EU) 2016/679.

Clause 3
Third-party beneficiaries

a. Data subjects may invoke and enforce these Clauses, as third-party beneficiaries, against the data exporter and/or data importer, with the following exceptions:
    i. Clause 1, Clause 2, Clause 3, Clause 6, Clause 7;
    ii. Clause 8 - Module One: Clause 8.5 (e) and Clause 8.9(b); Module Two: Clause 8.1(b), 8.9(a), (c), (d) and (e); Module Three: Clause 8.1(a), (c) and (d) and Clause 8.9(a), (c), (d), (e), (f) and (g); Module Four: Clause 8.1 (b) and Clause 8.3(b);
    iii. Clause 9 - Module Two: Clause 9(a), (c), (d) and (e); Module Three: Clause 9(a), (c), (d) and (e);
    iv. Clause 12 - Module One: Clause 12(a) and (d); Modules Two and Three: Clause 12(a), (d) and (f);
    v. Clause 13;
    vi. Clause 15.1(c), (d) and (e);
    vii. Clause 16(e);
    viii. Clause 18 - Modules One, Two and Three: Clause 18(a) and (b); Module Four: Clause 18.
b. Paragraph (a) is without prejudice to rights of data subjects under Regulation (EU) 2016/679.

Clause 4
Interpretation

a. Where these Clauses use terms that are defined in Regulation (EU) 2016/679, those terms shall have the same meaning as in that Regulation.

b. These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679.
c. These Clauses shall not be interpreted in a way that conflicts with rights and obligations provided for in Regulation (EU) 2016/679.

Clause 5
Hierarchy

In the event of a contradiction between these Clauses and the provisions of related agreements between the Parties, existing at the time these Clauses are agreed or entered into thereafter, these Clauses shall prevail.

Clause 6
Description of the transfer(s)

The details of the transfer(s), and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred, are specified in Annex I.B.

SECTION II – OBLIGATIONS OF THE PARTIES

Clause 8
Data protection safeguards

The data exporter warrants that it has used reasonable efforts to determine that the data importer is able, through the implementation of appropriate technical and organisational measures, to satisfy its obligations under these Clauses.

MODULE ONE: Transfer controller to controller

8.1 Purpose limitation

The data importer shall process the personal data only for the specific purpose(s) of the transfer, as set out in Annex I.B. It may only process the personal data for another purpose:

i. where it has obtained the data subject's prior consent;
ii. where necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings; or
iii. where necessary in order to protect the vital interests of the data subject or of another natural person.

8.2 Transparency

a. In order to enable data subjects to effectively exercise their rights pursuant to Clause 10, the data importer shall inform them, either directly or through the data exporter:
    i. of its identity and contact details;
    ii. of the categories of personal data processed;
    iii. of the right to obtain a copy of these Clauses;

iv. where it intends to onward transfer the personal data to any third party/ies, of the recipient or categories of recipients (as appropriate with a view to providing meaningful information), the purpose of such onward transfer and the ground therefore pursuant to Clause 8.7.

b. Paragraph (a) shall not apply where the data subject already has the information, including when such information has already been provided by the data exporter, or providing the information proves impossible or would involve a disproportionate effort for the data importer. In the latter case, the data importer shall, to the extent possible, make the information publicly available.
c. On request, the Parties shall make a copy of these Clauses, including the Appendix as completed by them, available to the data subject free of charge. To the extent necessary to protect business secrets or other confidential information, including personal data, the Parties may redact part of the text of the Appendix prior to sharing a copy, but shall provide a meaningful summary where the data subject would otherwise not be able to understand its content or exercise his/her rights. On request, the Parties shall provide the data subject with the reasons for the redactions, to the extent possible without revealing the redacted information.
d. Paragraphs (a) to (c) are without prejudice to the obligations of the data exporter under Articles 13 and 14 of Regulation (EU) 2016/679.

8.3 Accuracy and data minimisation

a. Each Party shall ensure that the personal data is accurate and, where necessary, kept up to date. The data importer shall take every reasonable step to ensure that personal data that is inaccurate, having regard to the purpose(s) of processing, is erased or rectified without delay.
b. If one of the Parties becomes aware that the personal data it has transferred or received is inaccurate, or has become outdated, it shall inform the other Party without undue delay.
c. The data importer shall ensure that the personal data is adequate, relevant and limited to what is necessary in relation to the purpose(s) of processing.

8.4 Storage limitation

The data importer shall retain the personal data for no longer than necessary for the purpose(s) for which it is processed. It shall put in place appropriate technical or organisational measures to ensure compliance with this obligation, including erasure or anonymisation of the data and all back-ups at the end of the retention period.

8.5 Security of processing

a. The data importer and, during transmission, also the data exporter shall implement appropriate technical and organisational measures to ensure the security of the personal data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access (hereinafter "personal data breach"). In assessing the appropriate level of security, they shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purpose(s) of processing and the risks involved in the processing for the data subject. The Parties shall in particular consider having

recourse to encryption or pseudonymisation, including during transmission, where the purpose of processing can be fulfilled in that manner.

b. The Parties have agreed on the technical and organisational measures set out in Annex II. The data importer shall carry out regular checks to ensure that these measures continue to provide an appropriate level of security.
c. The data importer shall ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.
d. In the event of a personal data breach concerning personal data processed by the data importer under these Clauses, the data importer shall take appropriate measures to address the personal data breach, including measures to mitigate its possible adverse effects.
e. In case of a personal data breach that is likely to result in a risk to the rights and freedoms of natural persons, the data importer shall without undue delay notify both the data exporter and the competent supervisory authority pursuant to Clause 13. Such notification shall contain i) a description of the nature of the breach (including, where possible, categories and approximate number of data subjects and personal data records concerned), ii) its likely consequences, iii) the measures taken or proposed to address the breach, and iv) the details of a contact point from whom more information can be obtained. To the extent it is not possible for the data importer to provide all the information at the same time, it may do so in phases without undue further delay.
f. In case of a personal data breach that is likely to result in a high risk to the rights and freedoms of natural persons, the data importer shall also notify without undue delay the data subjects concerned of the personal data breach and its nature, if necessary in cooperation with the data exporter, together with the information referred to in paragraph (e), points ii) to iv), unless the data importer has implemented measures to significantly reduce the risk to the rights or freedoms of natural persons, or notification would involve disproportionate efforts. In the latter case, the data importer shall instead issue a public communication or take a similar measure to inform the public of the personal data breach.
g. The data importer shall document all relevant facts relating to the personal data breach, including its effects and any remedial action taken, and keep a record thereof.

8.6 Sensitive data

Where the transfer involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions or offences (hereinafter "sensitive data"), the data importer shall apply specific restrictions and/or additional safeguards adapted to the specific nature of the data and the risks involved. This may include restricting the personnel permitted to access the personal data, additional security measures (such as pseudonymisation) and/or additional restrictions with respect to further disclosure.

8.7 Onward transfers

The data importer shall not disclose the personal data to a third party located outside the European Union (in the same country as the data importer or in another third country,

hereinafter “onward transfer”) unless the third party is or agrees to be bound by these Clauses, under the appropriate Module. Otherwise, an onward transfer by the data importer may only take place if:

i. it is to a country benefitting from an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 that covers the onward transfer;
ii. the third party otherwise ensures appropriate safeguards pursuant to Articles 46 or 47 of Regulation (EU) 2016/679 with respect to the processing in question;
iii. the third party enters into a binding instrument with the data importer ensuring the same level of data protection as under these Clauses, and the data importer provides a copy of these safeguards to the data exporter;
iv. it is necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings;
v. it is necessary in order to protect the vital interests of the data subject or of another natural person; or
vi. where none of the other conditions apply, the data importer has obtained the explicit consent of the data subject for an onward transfer in a specific situation, after having informed him/her of its purpose(s), the identity of the recipient and the possible risks of such transfer to him/her due to the lack of appropriate data protection safeguards. In this case, the data importer shall inform the data exporter and, at the request of the latter, shall transmit to it a copy of the information provided to the data subject.

Any onward transfer is subject to compliance by the data importer with all the other safeguards under these Clauses, in particular purpose limitation.

8.8 Processing under the authority of the data importer

The data importer shall ensure that any person acting under its authority, including a processor, processes the data only on its instructions.

8.9 Documentation and compliance

a. Each Party shall be able to demonstrate compliance with its obligations under these Clauses. In particular, the data importer shall keep appropriate documentation of the processing activities carried out under its responsibility.
b. The data importer shall make such documentation available to the competent supervisory authority on request.

Clause 10
Data subject rights

a. The data importer, where relevant with the assistance of the data exporter, shall deal with any enquiries and requests it receives from a data subject relating to the processing of his/her personal data and the exercise of his/her rights under these Clauses without undue delay and at the latest within one month of the receipt of the enquiry or request. The data importer shall take appropriate measures to facilitate such enquiries, requests and the exercise of data subject rights. Any information provided to the data subject shall be in an intelligible and easily accessible form, using clear and plain language.

b. In particular, upon request by the data subject the data importer shall, free of charge :
    i. provide confirmation to the data subject as to whether personal data concerning him/her is being processed and, where this is the case, a copy of the data relating to him/her and the information in Annex I; if personal data has been or will be onward transferred, provide information on recipients or categories of recipients (as appropriate with a view to providing meaningful information) to which the personal data has been or will be onward transferred, the purpose of such onward transfers and their ground pursuant to Clause 8.7; and provide information on the right to lodge a complaint with a supervisory authority in accordance with Clause 12(c)(i);
    ii. rectify inaccurate or incomplete data concerning the data subject;
    iii. erase personal data concerning the data subject if such data is being or has been processed in violation of any of these Clauses ensuring third-party beneficiary rights, or if the data subject withdraws the consent on which the processing is based.
c. Where the data importer processes the personal data for direct marketing purposes, it shall cease processing for such purposes if the data subject objects to it.
d. The data importer shall not make a decision based solely on the automated processing of the personal data transferred (hereinafter "automated decision"), which would produce legal effects concerning the data subject or similarly significantly affect him/her, unless with the explicit consent of the data subject or if authorised to do so under the laws of the country of destination, provided that such laws lays down suitable measures to safeguard the data subject's rights and legitimate interests. In this case, the data importer shall, where necessary in cooperation with the data exporter:
    i. inform the data subject about the envisaged automated decision, the envisaged consequences and the logic involved; and
    ii. implement suitable safeguards, at least by enabling the data subject to contest the decision, express his/her point of view and obtain review by a human being.
e. Where requests from a data subject are excessive, in particular because of their repetitive character, the data importer may either charge a reasonable fee taking into account the administrative costs of granting the request or refuse to act on the request.
f. The data importer may refuse a data subject's request if such refusal is allowed under the laws of the country of destination and is necessary and proportionate in a democratic society to protect one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679.
g. If the data importer intends to refuse a data subject's request, it shall inform the data subject of the reasons for the refusal and the possibility of lodging a complaint with the competent supervisory authority and/or seeking judicial redress.

Clause 11
Redress

a. The data importer shall inform data subjects in a transparent and easily accessible format, through individual notice or on its website, of a contact point authorised to

handle complaints. It shall deal promptly with any complaints it receives from a data subject.

b. In case of a dispute between a data subject and one of the Parties as regards compliance with these Clauses, that Party shall use its best efforts to resolve the issue amicably in a timely fashion. The Parties shall keep each other informed about such disputes and, where appropriate, cooperate in resolving them.
c. Where the data subject invokes a third-party beneficiary right pursuant to Clause 3, the data importer shall accept the decision of the data subject to:
    i. lodge a complaint with the supervisory authority in the Member State of his/her habitual residence or place of work, or the competent supervisory authority pursuant to Clause 13;
    ii. refer the dispute to the competent courts within the meaning of Clause 18.
d. The Parties accept that the data subject may be represented by a not-for-profit body, organisation or association under the conditions set out in Article 80(1) of Regulation (EU) 2016/679.
e. The data importer shall abide by a decision that is binding under the applicable EU or Member State law.
f. The data importer agrees that the choice made by the data subject will not prejudice his/her substantive and procedural rights to seek remedies in accordance with applicable laws.

Clause 12
Liability

a. Each Party shall be liable to the other Party/ies for any damages it causes the other Party/ies by any breach of these Clauses.
b. Each Party shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages that the Party causes the data subject by breaching the third-party beneficiary rights under these Clauses. This is without prejudice to the liability of the data exporter under Regulation (EU) 2016/679.
c. Where more than one Party is responsible for any damage caused to the data subject as a result of a breach of these Clauses, all responsible Parties shall be jointly and severally liable and the data subject is entitled to bring an action in court against any of these Parties.
d. The Parties agree that if one Party is held liable under paragraph (c), it shall be entitled to claim back from the other Party/ies that part of the compensation corresponding to its / their responsibility for the damage.
e. The data importer may not invoke the conduct of a processor or sub-processor to avoid its own liability.

Clause 13
Supervision

a. [Where the data exporter is established in an EU Member State:] The supervisory authority with responsibility for ensuring compliance by the data exporter with Regulation (EU) 2016/679 as regards the data transfer, as indicated in Annex I.C, shall act as competent supervisory authority.

b. The data importer agrees to submit itself to the jurisdiction of and cooperate with the competent supervisory authority in any procedures aimed at ensuring compliance with these Clauses. In particular, the data importer agrees to respond to enquiries, submit to audits and comply with the measures adopted by the supervisory authority, including remedial and compensatory measures. It shall provide the supervisory authority with written confirmation that the necessary actions have been taken.

SECTION III – LOCAL LAWS AND OBLIGATIONS IN CASE OF ACCESS BY PUBLIC AUTHORITIES

Clause 14
Local laws and practices affecting compliance with the Clauses

a. The Parties warrant that they have no reason to believe that the laws and practices in the third country of destination applicable to the processing of the personal data by the data importer, including any requirements to disclose personal data or measures authorising access by public authorities, prevent the data importer from fulfilling its obligations under these Clauses. This is based on the understanding that laws and practices that respect the essence of the fundamental rights and freedoms and do not exceed what is necessary and proportionate in a democratic society to safeguard one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679, are not in contradiction with these Clauses.
b. The Parties declare that in providing the warranty in paragraph (a), they have taken due account in particular of the following elements:
    i. the specific circumstances of the transfer, including the length of the processing chain, the number of actors involved and the transmission channels used; intended onward transfers; the type of recipient; the purpose of processing; the categories and format of the transferred personal data; the economic sector in which the transfer occurs; the storage location of the data transferred;
    ii. the laws and practices of the third country of destination– including those requiring the disclosure of data to public authorities or authorising access by such authorities – relevant in light of the specific circumstances of the transfer, and the applicable limitations and safeguards;
    iii. any relevant contractual, technical or organisational safeguards put in place to supplement the safeguards under these Clauses, including measures applied during transmission and to the processing of the personal data in the country of destination.
c. The data importer warrants that, in carrying out the assessment under paragraph (b), it has made its best efforts to provide the data exporter with relevant information and agrees that it will continue to cooperate with the data exporter in ensuring compliance with these Clauses.
d. The Parties agree to document the assessment under paragraph (b) and make it available to the competent supervisory authority on request.
e. The data importer agrees to notify the data exporter promptly if, after having agreed to these Clauses and for the duration of the contract, it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under paragraph (a), including following a change in the laws of the third country or a

measure (such as a disclosure request) indicating an application of such laws in practice that is not in line with the requirements in paragraph (a).

f. Following a notification pursuant to paragraph (e), or if the data exporter otherwise has reason to believe that the data importer can no longer fulfil its obligations under these Clauses, the data exporter shall promptly identify appropriate measures (e.g. technical or organisational measures to ensure security and confidentiality) to be adopted by the data exporter and/or data importer to address the situation.

- The data exporter shall suspend the data transfer if it considers that no appropriate safeguards for such transfer can be ensured, or if instructed by

- the competent supervisory authority to do so. In this case, the data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses. If the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise. Where the contract is terminated pursuant to this Clause, Clause 16(d) and (e) shall apply.

Clause 15

Obligations of the data importer in case of access by public authorities

15.1 Notification

a. The data importer agrees to notify the data exporter and, where possible, the data subject promptly (if necessary with the help of the data exporter) if it:
    i. receives a legally binding request from a public authority, including judicial authorities, under the laws of the country of destination for the disclosure of personal data transferred pursuant to these Clauses; such notification shall include information about the personal data requested, the requesting authority, the legal basis for the request and the response provided; or
    ii. becomes aware of any direct access by public authorities to personal data transferred pursuant to these Clauses in accordance with the laws of the country of destination; such notification shall include all information available to the importer.

b. If the data importer is prohibited from notifying the data exporter and/or the data subject under the laws of the country of destination, the data importer agrees to use its best efforts to obtain a waiver of the prohibition, with a view to communicating as much information as possible, as soon as possible. The data importer agrees to document its best efforts in order to be able to demonstrate them on request of the data exporter.
c. Where permissible under the laws of the country of destination, the data importer agrees to provide the data exporter, at regular intervals for the duration of the contract, with as much relevant information as possible on the requests received (in particular, number of requests, type of data requested, requesting authority/ies, whether requests have been challenged and the outcome of such challenges, etc.).

d. The data importer agrees to preserve the information pursuant to paragraphs (a) to (c) for the duration of the contract and make it available to the competent supervisory authority on request.
e. Paragraphs (a) to (c) are without prejudice to the obligation of the data importer pursuant to Clause 14(e) and Clause 16 to inform the data exporter promptly where it is unable to comply with these Clauses.

15.2 Review of legality and data minimisation

a. The data importer agrees to review the legality of the request for disclosure, in particular whether it remains within the powers granted to the requesting public authority, and to challenge the request if, after careful assessment, it concludes that there are reasonable grounds to consider that the request is unlawful under the laws of the country of destination, applicable obligations under international law and principles of international comity. The data importer shall, under the same conditions, pursue possibilities of appeal. When challenging a request, the data importer shall seek interim measures with a view to suspending the effects of the request until the competent judicial authority has decided on its merits. It shall not disclose the personal data requested until required to do so under the applicable procedural rules. These requirements are without prejudice to the obligations of the data importer under Clause 14(e).
b. The data importer agrees to document its legal assessment and any challenge to the request for disclosure and, to the extent permissible under the laws of the country of destination, make the documentation available to the data exporter. It shall also make it available to the competent supervisory authority on request.

c. The data importer agrees to provide the minimum amount of information permissible when responding to a request for disclosure, based on a reasonable interpretation of the request.

SECTION IV – FINAL PROVISIONS

Clause 16
Non-compliance with the Clauses and termination

a. The data importer shall promptly inform the data exporter if it is unable to comply with these Clauses, for whatever reason.
b. In the event that the data importer is in breach of these Clauses or unable to comply with these Clauses, the data exporter shall suspend the transfer of personal data to the data importer until compliance is again ensured or the contract is terminated. This is without prejudice to Clause 14(f).
c. The data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses, where:
    i. the data exporter has suspended the transfer of personal data to the data importer pursuant to paragraph (b) and compliance with these Clauses is not restored within a reasonable time and in any event within one month of suspension;
    ii. the data importer is in substantial or persistent breach of these Clauses; or

iii. the data importer fails to comply with a binding decision of a competent court or supervisory authority regarding its obligations under these Clauses.

- In these cases, it shall inform the competent supervisory authority of such non-compliance. Where the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise.

d. Personal data that has been transferred prior to the termination of the contract pursuant to paragraph (c) shall at the choice of the data exporter immediately be returned to the data exporter or deleted in its entirety. The same shall apply to any copies of the data.] The data importer shall certify the deletion of the data to the data exporter. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit the return or deletion of the transferred personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process the data to the extent and for as long as required under that local law.

e. Either Party may revoke its agreement to be bound by these Clauses where (i) the European Commission adopts a decision pursuant to Article 45(3) of Regulation (EU) 2016/679 that covers the transfer of personal data to which these Clauses apply; or (ii) Regulation (EU) 2016/679 becomes part of the legal framework of the country to which the personal data is transferred. This is without prejudice to other obligations applying to the processing in question under Regulation (EU) 2016/679.

Clause 17
Governing law

These Clauses shall be governed by the law of one of the EU Member States, provided such law allows for third-party beneficiary rights. The Parties agree that this shall be the law of _____ (*specify Member State*).

Clause 18
Choice of forum and jurisdiction

a. Any dispute arising from these Clauses shall be resolved by the courts of an EU Member State.
b. The Parties agree that those shall be the courts of _____ (*specify Member State*).
c. A data subject may also bring legal proceedings against the data exporter and/or data importer before the courts of the Member State in which he/she has his/her habitual residence.
d. The Parties agree to submit themselves to the jurisdiction of such courts.

APPENDIX

EXPLANATORY NOTE:
It must be possible to clearly distinguish the information applicable to each transfer or category of transfers and, in this regard, to determine the respective role(s) of the Parties as data exporter(s) and/or data importer(s). This does not necessarily require completing and signing separate appendices for each transfer/category of transfers and/or contractual relationship, where this transparency can [be] achieved through one appendix. However, where necessary to ensure sufficient clarity, separate appendices should be used.

ANNEX I

A. LIST OF PARTIES

Data exporter(s): [*Identity and contact details of the data exporter(s) and, where applicable, of its/their data protection officer and/or representative in the European Union]*

1. Name: …
   Address: …
   Contact person's name, position and contact details: …
   Activities relevant to the data transferred under these Clauses: …
   Signature and date: …
   Role (controller/processor): …
2. …

Data importer(s): [*Identity and contact details of the data importer(s), including any contact person with responsibility for data protection]*

1. Name: …
   Address: …
   Contact person's name, position and contact details: …
   Activities relevant to the data transferred under these Clauses: …
   Signature and date: …
2. Role (controller/processor): ……

B. DESCRIPTION OF TRANSFER

Categories of data subjects whose personal data is transferred

...

Categories of personal data transferred

...

Sensitive data transferred (if applicable) and applied restrictions or safeguards that fully take into consideration the nature of the data and the risks involved, such as for instance strict purpose limitation, access restrictions (including access only for staff having followed specialised training), keeping a record of access to the data, restrictions for onward transfers or additional security measures.

...

The frequency of the transfer (e.g. whether the data is transferred on a one-off or continuous basis).

...

Nature of the processing

...

Purpose(s) of the data transfer and further processing

...

The period for which the personal data will be retained, or, if that is not possible, the criteria used to determine that period

...

For transfers to (sub-)processors, also specify subject matter, nature and duration of the processing

...

C. COMPETENT SUPERVISORY AUTHORITY

Identify the competent supervisory authority/ies in accordance with Clause 13

…

ANNEX II - TECHNICAL AND ORGANISATIONAL MEASURES INCLUDING TECHNICAL AND ORGANISATIONAL MEASURES TO ENSURE THE SECURITY OF THE DATA

EXPLANATORY NOTE:
The technical and organisational measures must be described in specific (and not generic) terms. See also the general comment on the first page of the Appendix, in particular on the need to clearly indicate which measures apply to each transfer/set of transfers.

Description of the technical and organisational measures implemented by the data importer(s) (including any relevant certifications) to ensure an appropriate level of security, taking into account the nature, scope, context and purpose of the processing, and the risks for the rights and freedoms of natural persons.

[Examples of possible measures:

- *Measures of pseudonymisation and encryption of personal data*
- *Measures for ensuring ongoing confidentiality, integrity, availability and resilience of processing systems and services*

- *Measures for ensuring the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident*
- *Processes for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures in order to ensure the security of the processing*
- *Measures for user identification and authorisation*
- *Measures for the protection of data during transmission*
- *Measures for the protection of data during storage*
- *Measures for ensuring physical security of locations at which personal data are processed*
- *Measures for ensuring events logging*
- *Measures for ensuring system configuration, including default configuration*
- *Measures for internal IT and IT security governance and management*
- *Measures for certification/assurance of processes and products*
- *Measures for ensuring data minimisation*
- *Measures for ensuring data quality*
- *Measures for ensuring limited data retention*
- *Measures for ensuring accountability*
- *Measures for allowing data portability and ensuring erasure]*

For transfers to (sub-) processors, also describe the specific technical and organisational measures to be taken by the (sub-) processor to be able to provide assistance to the controller and, for transfers from a processor to a sub-processor, to the data exporter