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) transfer 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.

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

The Parties agree on the following contractual clauses on data protection (hereafter, "the Clauses") in order to adduce adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals concerned for the transfer by the Program Data Discloser(s), as defined in the Section 1. below, to the Institution and Investigator, of the Program Data on behalf of BIG.

Each party represents, warrants and undertakes to perform its obligations according to their respective responsibilities as defined in this Agreement, in accordance with Data Protection Laws, as defined in the Section 1. below. For the purposes of this Agreement, BIG on one hand, and the Institution and Investigator on the other, shall act as independent Data Controllers of the Personal Data transferred related to the Research Project. Should a third entity act as Program Data Discloser(s), such third entity shall be defined also as a separate Processor(s) on behalf of BIG for the transfer of the Program Data covered under this Agreement and its obligations will be an object of a separate agreement.

The Processing of Personal Data by the Institution and/or Investigator within the framework of this Agreement will be carried out only for the purposes of the Research Project, in accordance with the terms of this Agreement. Institution and Investigator will keep such Personal Data for the necessary period of carrying out the Research Project.

In the context of this Agreement, the Personal Data processed is data concerning health and genetic data of Study participants ('Data Subjects'), as well as data concerning the involved parties in the Agreement and their respective employees or collaborators working under their authority.

1. Definitions

For the purposes of the following Clauses:

(a) 'Data Discloser' means BIG and/or third entity on behalf of BIG transferring the Personal Data to the Data Receiver for the purposes of the Research Project;
(b) 'Data Receiver' means Institution and Investigator, i.e. Data Controller receiving the Personal Data from the Data Discloser;

The details of the transfer (as well as the Personal Data covered) are specified in the Exhibit A, which forms an integral part of these Clauses.

'**Data Controller'**, '**Data Processor'**, **'Data Security Breach'**, '**Personal Data'**, '**Processing'**, '**Technical and Organizational Measures'**, '**Supervisory Authority'** as well as the terms not defined in this Appendix related to data protection, shall have the meaning set forth in the General Data Protection Regulation (EU) 2016/679 with regard to the processing of personal data and on the free movement of such data.

'Data Protection Laws' means all applicable laws in relation to (a) data protection; (b) privacy; (c) restrictions on or requirements relating to the Processing of Personal Data of any kind including laws addressing identity theft or Data Security Breach, including but not limited to the General Data Protection Regulation (EU) 2016/679 with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

2. OBLIGATIONS OF INSTITUTION AND INVESTIGATOR

2.1 Institution and Investigator agree and warrant that:

(a) The Processing of Personal Data must be restricted to research experimentation in compliance with all 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 Harmonized 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), including any future enactments thereof. If Institution and/or Investigator cannot provide such compliance for whatever reasons, the Institution and/or Investigator agrees to inform promptly BIG of the Institution's and/or Investigator's inability to comply, in which case BIG is entitled to suspend the transfer of data and/or terminate the Agreement;

(b) The Institution and/or Investigator has no reason to believe that the legislation applicable to the Institution and/or Investigator prevents the Institution and/or Investigator from fulfilling the Institution's and/or Investigator's obligations under the Agreement, and that in the event of a change in this legislation which is likely to have a substantial adverse effect on the warranties and obligations provided by these Clauses, the Institution and/or Investigator shall promptly notify the change to BIG as soon as the Institution and/or Investigator becomes aware, in which case BIG is entitled to suspend the transfer of data and/or terminate the Agreement;

(c) The Institution and Investigator have implemented the Technical and Organizational Measures before Processing the Personal Data transferred.

2.2 Further Obligations of Institution's and Investigator

Institution's and Investigator further agree and warrant:

(a) that the Institution's and Investigator shall create and maintain a record of the Institution's and Investigator's Processing activities in relation to this Agreement; Institution's and Investigator shall make the record available to BIG, any auditor appointed by BIG and/or the Supervisory Authority on first request;

(b) that, in the event of sub-Processing, the Institution's and Investigator have previously informed BIG and obtained their prior written consent, unless the sub-Processor was already identified in the proposal;

(c) that the Institution's and/or Investigator shall inform BIG of any intended changes concerning the addition or replacement of an approved sub-Processor, thereby giving BIG the opportunity to object to such changes;

(d) that the Processing by the sub-Processor shall be carried out in accordance with these Clauses and the Institution's and/or Investigator shall enter into a legally binding written agreement with the sub-Processor which imposes the same obligations on the sub-Processor as are imposed on the Institution and/or Investigator under these Clauses. Institution and/or Investigator shall be fully liable for any acts and/or omissions of any sub-Processor engaged by the Institution and/or Investigator to the same extent as if the acts or omissions were performed by the Institution and/or Investigator;

(e) that Institution and/or Investigator shall send to BIG, upon request, a summary of any sub-Processor agreement(s) the Institution and/or Investigator concludes for the Processing of Personal Data under this Agreement;

(f) that the Institution and Investigator shall Process the Personal Data only for the purposes of the Research Project, according to the Data Protection Laws;

(g) that persons authorized to Process the Personal Data are bound by confidentiality obligations in relation to such Personal Data;

(h) that persons authorized to Process the Personal Data have been appropriately trained on the Processing of Personal Data;

(i) that the Institution and/or Investigator shall notify BIG within five (5) business days of the Institution and/or Investigator's receipt of any communication from an individual or government authority relating to Personal Data. Institution and/or Investigator shall not respond to any such request unless obligated to do so under applicable laws or requested to do so by BIG. Institution and/or Investigator shall provide reasonable and timely assistance to help BIG to respond to any such requests related to Personal Data where BIG has a legal obligation to respond within a given timeframe;

(j) that the Institution and/or Investigator shall assist BIG by appropriate Technical and Organizational Measures, for the fulfilment of BIG's obligation to respond to requests for exercising the Data Subject's rights;

(k) that the Institution and/or Investigator shall cooperate with BIG in order to assist BIG in assuring compliance with BIG's obligations under applicable Data Protection Laws regarding the deletion or the return of Personal Data after completion of the approved Research Project;

(l) that the Institution and/or Investigator shall make available to the Data Subject upon request a copy of these Clauses, or any existing contract for sub-Processing, unless the Clauses or contract contain commercial information, in which case the Institution and/or Investigator may remove such commercial information, and a summary description of the security measures in those cases where the Data Subject is unable to obtain a copy from BIG;

(m) that at the request of BIG, the Institution and/or Investigator shall submit sufficient information about the Processing activities covered by these Clauses in order to demonstrate compliance and shall contribute to audits and/or inspections which shall be carried out by BIG or another auditor mandated by BIG. Institution and/or Investigator shall immediately inform BIG if, in Institution and/or Investigator's opinion, an instruction in the context of such audit infringes the Data Protection Laws. In case of audits conducted by BIG, such audits shall be done at BIG's own expense and will be notified to the Institution and/or Investigator with reasonable prior notice. Audits at the request of a

data protection Supervisory Authority may be requested at any point in time by the data protection Supervisory Authorities or following a Data Security Breach. Following an audit conducted by data protection Supervisory Authority, if applicable, BIG shall notify Institution and/or Investigator of the manner in which Institution and/or Investigator does not comply with any of these Clauses. Upon such notice, Institution and/or Investigator shall make any necessary changes to ensure compliance with such obligations;

(n) to handle promptly and properly all inquiries from BIG and/or Program Data Discloser relating to Institution and/or Investigator's processing of the Personal Data subject to the transfer and to abide by the advice of any Supervisory Authority with regard to the Processing of the Personal Data transferred;

(o) onward transfers - Institution and Investigator shall comply with the obligations of Chapter V of the GDPR in relation to any transfer of personal data to third countries or international organisations located outside of the European Union.

2.3 Security of Processing

Institution and/or Investigator shall implement appropriate Technical and Organizational measures to ensure a level of security appropriate to the risk for the Personal Data transferred, such as pseudonymisation, encryption, back-up or disaster recovery.

Institution and/or Investigator shall notify BIG within twenty-four (24) hours of becoming aware of any Data Security Breach and such notification will include, where possible, the approximate number of Data Subjects concerned and approximate number of Personal Data concerned, the impact and likely consequences on BIG, the affected Data Subjects by the Data Security Breach and the corrective action to be taken by the Institution and/or Investigator.

Institution and/or Investigator shall promptly implement, at Institution's and/or Investigator's expense (to the extent that the Data Security Breach was due to a breach of obligations under this Agreement), all corrective measures to necessary remedy the causes of such a breach and shall consult in good faith with BIG as regarding what remediation efforts may be necessary.

Institution and/or Investigator shall ensure that such remedy efforts provide for, without limitation, prevention of the recurrence of the same type of Data Security Breach and inform BIG of all corrective measures implemented and remediation efforts undertaken.

Exhibit A

DESCRIPTION OF THE TRANSFER OF PERSONAL DATA

Data subject

The personal data transferred concern the following categories of data subjects:

- Study Subjects
- Employees of the Data Discloser and Data Receiver involved in the Agreement

Purposes of the transfer(s)

The transfer is made for the following purposes:

- Research Project
- Data Transfer Agreement

Categories of data

The personal data transferred concern the following categories of data:

- Health Data
- Administrative Data

Recipients

The Personal Data transferred may be disclosed only to the following recipients or categories of recipients:

- The Parties to the Agreement and their employees/collaborators directly involved in the activities foreseen in the Agreement

Sensitive data (if appropriate)

The personal data transferred concern the following categories of sensitive data:

Health Data

Data Protection registration information of data exporter (where applicable)

NA

Additional useful information (storage limits and other relevant information)

As long as required for the performance of the Research Project or for the period required by Applicable Law.

Contact points for data protection enquiries

Data Receiver

[To be inserted]

Data Discloser

BIG aisbl,

20, Rue de Bretagne / Bretagnestraat,

1200 Brussels, Belgium