Policy for Access to Study Data and Biological Samples

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APPROVAL

First Name Last Name	Function	Signing reason	Date and Signature
Maria Rojo Pardillo	Project Manager	☒ I am the author of this document. ☐ I have reviewed this document. ☐ I approve this document.	13.07.26.
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DOCUMENT HISTORY

Effective Date	Author	Version No.	Description of Changes
13-Jul-2026	Maria Rojo Pardillo	1	The Policy for Access to Study Data and Biological Samples was originally developed by BIG. Following the sponsorship transition, all logos, references, and contact information have been updated to reflect the new sponsor, IJB.

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1 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 Institut Jules Bordet (IJB) and the academic partners on behalf of the Steering Committee (SC) in a specialised 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.

2 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:

Research proposals should be submitted using the Research Proposal Application Form, as described in https://aurora-ctc.hubruxelles.be.

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 (IJB).

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 IJB team will perform a feasibility review of the RPPs (including 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, IJB and the data transferring entity (if other than IJB) 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 to this Policy) 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 IJB'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 to the present Policy.

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 IJB of planned Publication/Presentation before submission to a journal/conference, for review as follows:

  o 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.

  o 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 all the entities funding the Program (to be asked to IJB at aurora.program@hubruxelles.be) and a reference to IJB 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 IJB) 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 1.

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 IJB 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.

3 PROCEDURES FOR SUBMISSION OF RPPS UNTIL DATA/SAMPLE TRANSFER

• Researchers must fill in the Research Proposal Application Form providing all required information and submit the proposal to the Research Project Proposal Administrator (RPPA) at IJB, 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 15 working days after the proposal. In case the requested data or RP BS

are not available, the researcher will be informed about the rejection within 15WD after the submission deadline.

➢ For RPPs requiring access to SD only: RPPs will be reviewed within 15 WD.

• 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 IJB, the Data transferring entity (if other than IJB) 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.

4 LIST OF ABBREVIATIONS

Terms	Definitions/meanings
BS	Biological Samples
DTA	Data Transfer Agreement
IJB	Institut Jules Bordet
IBBL	Integrated Biobank of Luxemburg
ICMJE	International Committee of Medical Journal Editors
IPR	Intellectual Property Rights
MTA	Material Transfer Agreement
RP	Research Project
RPP	Research Project Proposal

Terms	Definitions/meanings
RPPA	Research Project Proposal Administrator
SC	Steering Committee
SD	Study Data
WD	Working Days

5 APPENDIX

5.1 APPENDIX I: Intellectual Property Rights for RP

Defined terms used in this Appendix I shall have the meaning provided for them in the Policy itself unless otherwise specified below.

For the purpose of this Appendix, the following definitions apply:

"AURORA Sites" means Sites and Independent Sites participating in the AURORA study.

"AURORA Partners" means all Group, Sites and Independent Sites participating in the AURORA study.

"Background" means property of any kind (e.g. experiments, results, tests, trails, 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 study and which is needed for carrying out a Research Project or for a Foreground use.

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

"IJB Sites" means those sites affiliated with IJB Groups for the purposes of the AURORA study, whether they are contracting with the IJB Group or not.

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

"Foreground" means any IPR which is generated within a certain RP.

"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 an IJB Group in the context of the AURORA study.

"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 Data" means all data, in any form, collected regarding the patients recruited within the framework of the AURORA study, 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 AURORA study.

Principles

1. All Program Data are owned by IJB. All Program Data are deemed confidential information of IJB.
2. BS are stored in an independent biorepository, under the custodianship of IJB on behalf of the SC, which is responsible for the governance of the BS. 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 BS at all times. Access to such BS for RP shall be granted according to the present Policy.
3. AURORA Partner(s), academic (not being an AURORA Partner) or commercial entities requiring access to and use of the Program Data for conducting a RP shall be granted a non-exclusive, non-sublicensable, non-transferable license from IJB through an appropriate written agreement including the detailed terms and conditions of such a license, as well as the provisions indicated in the section "Agreements" of the present Policy.

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 RP, but for no other purpose, to the AURORA Partners carrying out such RP.

Each AURORA Partner may grant, freely or under negotiated terms and conditions, at its own discretion, a license to use its Background and/or Know-How to any academic (non-AURORA) or commercial entity(-ies) requiring the rights to such use for carrying out a RP.

Foreground

A. IT Platform

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

B. Molecular Advisory Board ('MAB') input

The MAB set in place for the AURORA study 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 IJB.

Research Projects

As a general principle:

1. All IPR generated by a RP shall be owned either by i) the AURORA Partner(s), the academic or the commercial entity(-ies) conducting such RP, solely or jointly, depending on whether there is a collaboration in place or not, or by ii) the entity(-ies) identified by and agreed between the AURORA Partner(s), the academic or the commercial entity(-ies) conducting such Research Project ("IPR Owner(s)").

In such case:

a) a fully paid, worldwide, non-exclusive, non-transferable license to use all data and results generated within the framework of a RP for academic research and teaching purposes only, shall be granted to all AURORA Partners;

b) should the results of a Research Project lead to a Commercial Use, and provided that IPR Owner(s) is/are not restricted for doing so by contractual commitments towards third party(-ies), the IPR Owner(s) hereby grant(s) to IJB a right to share in the Net Royalties derived from the Commercial Use.

2. IJB shall be notified in writing of any IPR 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.

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 IJB 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 IJB 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 IJB 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, IJB 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.

If IJB 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 IJB, 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.

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 IJB if IJB 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 IJB (as appropriate), and for IJB to file, continue prosecution or maintain such patent application or patent.

The IPR Owner(s) filing the patent shall bear all Licensing Costs for the intellectual property.

Subject to the following paragraph, and provided that IPR Owner(s) is/are not restricted for 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 IPR, calculated as follows, shall be granted to IJB:

IJB shall receive annual payments of ten percent (10%) of all Net Royalties.

IJB shall receive payment of IJB's share for any calendar year not later than April 30 of the following calendar year.

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