AURORA

Policy for Access to Study Data and Biological Samples

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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,
    - an assessment of clinical data and/or samples' derived data and/or samples availability will be made,
    - 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 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 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 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 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 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 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.