HEALEY ALS Platform Trial Biosample Sharing Policy

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1. Policy Statement

Sharing biosamples and associated study data from the HEALEY ALS Platform Trial is central to its mission to advance ALS science. The HEALEY ALS Platform Trial Biosample Sharing Policy is designed by the HEALEY ALS Platform Biomarkers and Outcome Measures Task Force and codified in regimen documents, in accordance with Regimen Partner contractual agreements.

2. Scope

This policy applies to sharing of biosamples and associated de-identified study data from the HEALEY ALS Platform Trial biorepository and will follow the Data & Report Sharing Policy for the HEALEY ALS Platform Trial, since biosamples are invariably shared in conjunction with associated clinical data. Biosamples include cerebrospinal fluid, plasma, serum, whole blood, urine, and isolated DNA. (As a point of clarification, existing genomic data is considered "data" and will be managed according to data sharing policies.)

The sharing of biosamples and associated data will be consistent with MGH policy, the informed consent form, or any IRB-approved waiver of authorization, and applicable law and pursuant to a written agreement with the recipient that contains appropriate terms and conditions regarding the privacy and security of human subjects derived data and materials.

3. Definitions

Study Regimen: A specific regimen defined by its Regimen-specific Appendix to the HEALEY ALS Master Protocol.

Regimen Screening Data: Both Master Protocol-level screening data and regimen-specific screening data for all participants assigned to the Study Regimen.

Study Treatment Data: Data for participants in the active treatment group(s) in the Study Regimen.

Study Pre-Treatment Data: Data from the pre-treatment screening and baseline visits of participants in the active treatment group(s) in the Study Regimen.

Study Placebo Data: Data for participants in the placebo group(s) in the Study Regimen.

HEALEY Placebo Data: Pooled Study Placebo Data from all regimens within the HEALEY ALS Platform Trial.

Shared Placebo Data: The subset of HEALEY Placebo Data shared for analysis of the Study Regimen from other regimens within the HEALEY ALS Platform Trial.

Study Data: Regimen Screening Data, Study Treatment Data, Study Placebo Data, and Shared Placebo Data, analysis data derived from these sources

4. Policy

PART I: BIOSAMPLE AVAILABILITY

For most study regimens, the designation of samples collected for a regimen will be split between the Regimen-specific Appendix and Master Protocol.

Biosamples designated to the Master Protocol fall under the guardianship of MGH.

Biosamples designated to the Regimen-specific Appendix fall under the guardianship of the Regimen Partner. This policy does not apply to Regimen Partner-designated biosamples under the Regimen Partner's guardianship. Those biosamples will be utilized/shared per the Regimen Partner's SOPs, the Regimen Partner contractual agreement, and participant consent. A Regimen Partner may choose to donate their designated biosamples to the HEALEY ALS Platform Trial Biorepository, thereby transferring guardianship to MGH.

Upon completion of a regimen, the samples under MGH guardianship can be made available to researchers at academic and/or non-profit organizations for approved research as indicated below.

Biosamples for a given regimen will only be shared with **academic and non-profit** entities once the placebo data from that regimen are "retired" (i.e., no longer in use for ANY regimen analysis) AND the Biomarkers and Outcome Measures Task Force has decided that sharing biosamples from the regimen is permitted. Sharing may be delayed even after placebo data for a regimen have been "retired" for a variety of reasons, including the ongoing clinical development of the investigational product.

Only de-identified study placebo data and study pre-treatment data may be provided to accompany biosamples.

Biosamples and accompanying de-identified study placebo data and study pre-treatment data can be requested by:

- the Regimen Partner during or following conclusion of the regimen. Request may include access to HEALEY placebo biosamples and associated data that contributed to their regimen analysis. (See PART II below)
- all other non-profit applicants, after the placebo data from the regimen are retired. (See PART III below)

Standard charges for sample access will be assessed per vial and may be adjusted for specific requests based on complexity. Standard charges be reviewed and updated every two years.

PART II: REGIMEN PARTNER BIOSAMPLE SHARING

A Regimen Partner has full access to Regimen Partner-designated biosamples at any time, pursuant to the contract and IRB for the regimen.

Regimen partners may request Master Protocol biosamples from their regimen (active and placebo) +/- shared HEALEY placebo samples during or after the conclusion of their Regimen, again, pursuant to appropriate IRB and contractual oversight. These biosamples will be requested using the Biosample Sharing Request Form. These will be reviewed directly by the HEALEY ALS Platform Trial Biomarkers and Outcome Measures Task Force.

PART III: NON-PROFIT BIOSAMPLE SHARING

Biosamples from the HEALEY ALS Platform Trial biorepository, where they are stored after the conclusion of a given Regimen, will be available for sharing, as outlined in Part I above.

The following additional considerations may affect review and approval of biosample requests or distribution of samples for approved projects:

- **Samples will only be shared with academic and non-profit entities.**
- Because biosamples are a limited resource, the Biomarkers & Outcome Measures Task Force may take into account sample availability and competing uses.
    - Requests should be accompanied by a scientific question of interest.
    - Reviews will be carried out confidentially. However, if there is a substantial overlap in projects, the Biomarkers and Outcome Measures Task Force or Executive Committee could decide to reach out to investigators to inquire about interest in collaborating with other groups performing similar analyses. If requestors choose not to collaborate, requests may be denied to avoid duplicative use of biosamples.
    - Requestors must have secured or have plans for securing the funding to support the project. The source of the secured funding must be provided.
- Biosamples will only be shared for purposes covered by the Informed Consent for the HEALEY ALS Platform Trial.
- Prior to receipt of biosamples, requestors are to have an approval or exemption from their IRB or Ethics Board of Record for the project and an appropriate executed material transfer agreement with MGH.

Part IV: BIOSAMPLE SHARING PROCEDURES

The Application Process:

To request biosamples and associated de-identified research data, investigators must submit:

- A completed HEALEY ALS Platform Trial Biosample Sharing Request Form
- The principal investigator's CV or biosketch.
- Verification of secured funding or outline of plans to secure funding to support the project.
- Upon request, the PI will produce verification that the research will be conducted at and on behalf of academic and/or non-profit entities, only.

- The completed request forms are submitted to the HEALEY ALS Platform Trial Biomarkers and Outcome Measures Task Force at to HealeyAMGCenterforALS@mgh.harvard.edu.

- An internal feasibility review of the request will be completed to determine the availability of biospecimens, and to verify the forms are completed correctly.
    - If the requested biospecimens are not available, the request will be declined as unfeasible and will not move forward to formal review and/or modifications to the applications may be requested to make the request feasible.
- Completed applications and the completed Feasibility Report are then forwarded to the HEALEY ALS Platform Trial Biomarkers and Outcome Measures Task Force for review. Proposals for collaborative projects may require review by the HEALEY Platform Trial Executive Committee.
- After formal review, a summary recommendation is passed along to the Master Protocol Sponsor or designee for final decision and signature.

Approval letters will outline any revisions from the submitted request or caveats associated with the provision of biosamples or data.

If a request is denied, investigators may submit a new application for a revised request. Note that denied requests may not be addressed by rebuttal.

Biosample requests will be reviewed within a reasonable timeframe.

Post-Approval Sharing Procedures:

After a biosample request is approved, the following must be completed prior to the distribution of biosamples and associated de-identified data:

- A Material Transfer Agreement (MTA) will be executed between MGH and the requesting organization. MGH will initiate the MTA.
    - Use of the biosamplesand de-identified data will be restricted to the project as approved by the the HEALEY ALS Platform Trial Biomarkers and Outcome Measures Task Force and the Master Protocol Sponsor or designee.
    - Biospecimen sharing charges, if applicable, will be delineated within the MTA.
    - If a project involves multiple collaborators, MGH may request that one party serves as the principal investigator for the over-arching project, including oversight of work done by collaborators.

  NOTE: For investigators within the Mass General Brigham (MGB), a standard Letter of Transfer (LOT) rather than a Material Transfer Agreement (MTA) may be utilized.
- The requestor must provide the approval or exemption from the requestor's IRB or Ethics Board of Record. It is recommended that this document be provided prior to initiating the resource transfer agreement.
- The requestor must provide verification of secured funding. If funding is not secured at time of approval, biosamples may be committed up to six months.

- Invoicing of biosample sharing charges will occur after distribution of the biosamples and data, if applicable.

Acknowledgement and Reporting

Acceptance of HEALEY ALS Platform Trial participant-level biosamples obligates the recipient to include an acknowledgement of the Healey & AMG Center for ALS at Mass General and appropriate grant citations in accordance with the HEALEY ALS Platform Trial Publication Policy in any presentation or publication that may result from use of the requested biosamples.

The recipient agrees to follow the HEALEY ALS Platform Trial Publication Policy. The recipient must also notify the HEALEY Platform Trial Executive Committee with publication details (reference or PubMedCentral ID#) and provide a copy of the publication so productivity derived from our resources can be reported.

Furthermore, the recipient will report any funding resulting from this research now or in the future, with details (grant title, sponsor, number, dollar total, dates) so productivity derived from our resources can be reported.

No sharing of biosamples with a third party or analysis beyond what is requested and approved is allowed. To request any modifications to the approved proposal a new application must be submitted as outlined above.

Biosample Data Return:

Requestors will be required to return analytical results from analysis of requested biosamples to the Biomarkers and Outcome Measures Task Force or designee prior to receipt of matching clinical data and unblinding of biosample identifiers unless the Biomarkers and Outcome Measures Task Force or designee specifies otherwise in writing. Recipient can specify that after an agreed upon period, analytical results can be shared with third parties at HEALEY ALS Platform Trial PI's discretion to support further ALS research or that analytical results can be used internally at the Healey & AMG Center only.

5. Poilcy Rewiew

This policy will be reviewed at least once every two years and updated by the Executive Committee as appropriate.

6. Document History

Version	**Change Type** New, Revise, Review Admin	**Issue Date**	**Effective Date**	**Summary**
Version 1.0	Original	18-Feb-2025	18-Mar-2025	Not Applicable
Version 2.0	Revised	23-May-2025	23-Jun-2025	Include definition of Study Pre-Treatment Data