Sample Use Publication Acknowledgement:
The HEALEY ALS Platform Trial requires that all journal publications that result from the use of Platform Trial biosamples acknowledge the HEALEY ALS Platform Trial Sample Repository as their biosample source with the following sentence: "Biosamples used for this analysis were obtained from the HEALEY ALS Platform Trial Sample Repository."

Please reference the HEALEY ALS Platform Trial Publication Policy (https://www.massgeneral.org/assets/mgh/pdf/neurology/als/healey_platform_trial_publication%20policy.pdf) to ensure compliance with all publication policies.

Submission Procedures:
Please complete the Biosample Sharing Request Form and submit to HealeyAMGCenterforALS@mgh.harvard.edu.

The form will be reviewed by the HEALEY ALS Platform Trial Biomarkers & Outcome Measures Task Force. The Biomarkers & Outcome Measures Task Force meet at least monthly to review submitted requests.

Restrictions:
Biosamples cannot be sold or shared beyond the specified use in this approved request. Fully executed Materials Transfer Agreement(s) (MTA) or other applicable agreement may be required prior to provision of biosamples or data.

Biosamples will only be shared with associated Regimen Partners or non-profit institutions and accompanying clinical information will be de-identified. Longitudinal samples may be shared from placebo and/or treated participants. Additional restrictions on associated data accompanying longitudinal samples from treated participants for non-profit institutional requests: only pre-treatment screening and baseline visit data will be shared.

Sharing of biosamples or study data will be consistent with MGH policy, the ICF, 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.

Disclaimer Statements:
Biosamples collected from the HEALEY ALS Platform Trial will be stored in the HEALEY ALS Platform Trial Sample Repository located as Massachusetts General Hospital. The biosamples and the corresponding study data collected, stored, and shared are performed under IRB approved protocols and in accordance with HIPAA.

While the HEALEY ALS Platform Trial Sample Repository does not knowingly distribute biofluid samples from research participants known to be infectious, it is ultimately the responsibility of the recipient to employ proper biosafety handling techniques.

SUBMISSION PROCEDURE:

Please submit the Biosample Request Form to HealeyAMGCenterforALS@mgh.harvard.edu for distribution to the Biomarkers and Outcome Measures Task Force for review to ensure they comply with HEALEY ALS Platform Trial requirements for biosample sharing in accordance with the HEALEY ALS Platform Trial Biosample Sharing Policy.

Submitted by (Name):
Submitter Title:
Submitted by (Institution/Organization):
Contact email:
Contact Telephone:
Date of Request:

Lab Shipping Address (include Attention to information):

Lab Contact name, email, and phone (if different from above):

Is your organization part of the HEALEY ALS Platform Trial? ☐ **Yes** ☐ **No**

Do you have funding to support the project? ☐ **Yes** ☐ **No**

If yes, please provide funding source:

Is part of this project funded by industry? ☐ **Yes** ☐ **No**

If yes, please provide the name of the industry:

Project/Request Title:

Project/Request Aims:
Please provide up to 3 concise aims for your project (300-character limit per aim). At least one aim must be provided.
Project Aim 1:

Project Aim 2:

Project Aim 3:

Purpose

What is the purpose of this biosample request? Check all that apply.

☐ Current or planned research ☐ Preliminary feasibility ☐ Data exploration
☐ Grant application ☐ Journal publication ☐ Abstract submission
☐ Clinical trial ☐ Regulatory requirement ☐ Other _____

BIOSAMPLE TYPE AND VOLUME

Please specify the minimum volume of sample needed per biosample.

Please provide a justification for the volume(s) indicated below in the Experimental Plan.
CSF is collected in polypropylene and stored in 250uL aliquots. P/S/U are stored in 500uL aliquots.

☐ Cerebrospinal Fluid (CSF) Volume per Biosample: _____ microliters (uL)
☐ Plasma Volume per Biosample: _____ microliters (uL)
☐ Serum Volume per Biosample: _____ microliters (uL)
☐ Urine Volume per Biosample: _____ microliters (uL)
☐ Whole Blood Volume per Biosample: _____ microliters (uL)
☐ DNA Isolate Volume per Biosample: _____ microliters (uL)

If you are requesting more than one biosample type, do you need matched biosamples?
(for example, two biofluids from the same participants at each timepoint) ☐ **Yes** ☐ **No**

If yes, and a match is unavailable, will unmatched biosamples be acceptable? ☐ **Yes** ☐ **No** ☐ **N/A**

STUDY REGIMEN:

Each regimen has a randomized controlled trial and an open label extension/active treatment extension for all who complete RCT and choose to enroll. Please include the study regimen, company name, and study drug.

☐ Any Available Regimens, or

Specific Regimens:

☐ Regimen A (UCB/Zilucoplan) ☐ Regimen B (Biohaven/Verdiperstat)

☐ Regimen C (Clene/CNM-Au8) ☐ Regimen D (Prilenia/Pridopidene)

☐ Regimen E (Seelos/Trehalose) *placebo only*

BIOSAMPLE TIME POINTS:

Randomized Placebo Controlled Trial - Check all timepoints and provide number for participant biosamples requested.

	Baseline	*Week 8*	*Week 16*	*Week 24*
Blinded Mix (Placebo & Study Drug) (max 160)	☐ #_____	☐ #_____	☐ #_____	☐ #_____
- OR -				
Placebo Only (max 40)	☐ #_____	☐ #_____	☐ #_____	☐ #_____
Study Drug Only (max 120)	☐ #_____	☐ #_____	☐ #_____	☐ #_____

Open Label Extension/Active Treatment Extension - Please check all timepoints for which you want participant biosamples.

	*Baseline**	*Week 16*	*Week 28*	*Week 52*
Study Drug (max 100-160 depending upon enrollment)	☐ #_____	☐ #_____	☐ #_____	☐ #_____

**There is no true Baseline collection in the OLE, however the WK24 collection in the randomized controlled portion occurs at the same time as starting the OLE and may serve as a Baseline for those on placebo.*

If you are requesting biosamples from only a subset of participants, are there any specific requirements for the biosamples (e.g., time of collection, not taking Riluzole)? ☐ **Yes** ☐ **No** ☐ **N/A**
If yes, please list the specific requirements:

Any other explanatory notes?

EXPERIMENTAL PLAN:

Please provide a brief explanation of your proposed use of the biosamples. This should include rationale, preliminary data/evidence of feasibility, the relevance to the regimen, and outline of experimental approach, and justification of biosample size and volume. *Please limit explanation to no more than one page.*

Are you a Regimen Partner requesting to analyze Biosamples as the regimen is ongoing? ☐ **Yes** ☐ **No**

If Yes, Analyzing biosamples during an ongoing regimen can raise issues of unblinding under certain circumstances. If there is a justified reason for analysis of biosamples during the ongoing RCT, when the trial is blinded, we will need to work with your team to optimize procedures to maintain the blind and enact appropriate firewalls. To help us understand the plan, please answer these questions:
Skip if analyzing at the conclusion of the regimen – after regimen database lock.

1) **Why can the biosamples not be analyzed at the conclusion of the regimen?**

2) **What measures do you propose to mitigate a potential unblinding effect?**

FOR INTERNAL USE ONLY

Date Request Received: _____
Date of Review: _____

Biosample Use – is the purpose sufficiently justified and consistent with applicable policies?
☐ Yes ☐ No *(if no, please describe reason for denial)*:

Operationally feasible?
☐ Yes ☐ No *(if no, please describe reason for denial)*:

Comments/updates to biosample request:

Is there a cost associated with this request? ☐ **No** ☐ **Yes, amount: _____**

☐ **Approved** ☐ **Denied** **Reason for Denial:**

_____

Approved By Merit Cudkowicz:
Signature and Date:
Role: Sponsor