

## **APPENDIX I**

### **HEALEY ALS Platform Trial Publication Contract Terms**

The HEALEY ALS Platform Trial publication policy adheres to the contractual terms of our Master Clinical Trial Agreement (MCTA) with sites and the Clinical Research Services agreements with industry partners.

**From MCTA** (Page 7 HealeyCenter\_Master Clinical Trial Agreement\_10.22.19\_FINAL; Healey Center Insight record #233954):

#### **Article 14. Publications and Copyrights**

Each Study Regimen is a multi-site study and a collaborative publication is anticipated. Site agrees that it shall delay publication using its own Study Treatment Data until such time as the collaborative publication is released or eighteen (18) months after the conclusion of the Study Regimen, whichever occurs first. In order to ensure the integrity of meaningfulness of the platform trial model, Site agrees that they shall delay publication of any Study Placebo Data or Healey Placebo Data until such time as the HEALEY ALS Platform Trial Executive Committee grants explicit permission to publish it.

The HEALEY ALS Platform Trial Executive Committee will determine a publication strategy and assume oversight of this Article 14. A “Study Publication” is any proposed abstract, manuscript, presentation, publication or similar material containing Study Regimen Data.

- a. Review and Authorship. All Study Publications must comply with the terms and conditions of the Master Site Clinical Trial Agreement and are thus subject to review by the HEALEY ALS Platform Trial Executive Committee, Study stakeholders and Company. Authorship shall be in accordance with the accepted ICMJE standards.
- b. Publication Review. All Study Publications shall be submitted to the HEALEY ALS Platform Trial Executive Committee for review by the HEALEY ALS Platform Trial Executive Committee at least forty-five (45) days prior to the submission of the Study Publication. Healey Center shall advise the Site within forty-five (45) days of receiving any Study Publication if the Study Publication: (i) contains or discloses any potentially patentable inventions (“Patentable Material”), or (ii) contains any Healey Center or Company Confidential Information. Site will delete any Patentable Material or Confidential Information.
- c. Company shall be entitled to review such Study Publications solely for the purposes of reviewing for use of Company’s name, for identifying Company’s Confidential Information, which shall be removed from the publication upon Company’s request; and to identify any patentable Inventions; and to provide any other comments Company desires to provide, provided that MGH and the HEALEY ALS Platform Trial Executive Committee shall have no obligation to address any such additional comments beyond considering them in good

faith. Any Company may request that their name be included or omitted in a Study Publication in accordance with acceptable standards and publication policies.

In the event Site Investigator independently publishes in accordance with this Article, Site agrees that the support of the Healey Center shall be acknowledged whenever research findings funded in whole or in part by a Task Order are published. Site shall acknowledge the support of Healey Center whenever publicizing the work based on, or developed under a Task Order, in any media, whether copyrighted or not, by including an acknowledgment substantially as follows:

*" This investigation was supported by The Sean M. Healey and AMG Center for ALS and (insert other supporters, if applicable – consult MGH Study Administrator). "*

Site grants to MGH an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under a Task Order for educational and research purposes, including the creation of derivative works.

### **From Industry Agreement:**

#### **Article 12:**

Each Study Regimen is a multi-site study and a collaborative publication is anticipated. Company and Sites agree that they shall delay publication of the Study Regimen Treatment Data until such time as the collaborative publication is released or eighteen (18) months after the conclusion of the Study Regimen, whichever occurs first. In order to ensure the integrity of meaningfulness of the platform trial model, Company and Sites agree that they shall delay publication of any Study Regimen Placebo Data until such time as the HEALEY ALS Platform Trial Executive Committee grants explicit permission to publish it.

The HEALEY ALS Platform Trial Executive Committee will determine a publication strategy and assume oversight of this Article 12. A "Study Publication" is any proposed abstract, manuscript, presentation, publication or similar material containing Study Regimen Data.

12.1. Review and Authorship. All Study Publications are subject to review by the HEALEY ALS Platform Trial Executive Committee, Study stakeholders and Company. Authorship shall be in accordance with the accepted ICMJE standards. Company shall be entitled to review such Study Publications solely for the purpose of identifying Company's

Confidential Information, which shall be removed from the publication upon Company's request; and to identify any patentable Inventions, which shall be addressed as described in Article 11; and to provide any other comments Company desires to provide, provided that MGH and the Healey ALS Platform Trial Executive Committee shall have no obligation to address any such additional comments beyond considering them in good faith.

12.2. Publication Approval. All Study Publications shall be submitted to the Company for review under Section 12.1, and to the HEALEY ALS Platform Trial Executive Committee for review



and approval by the HEALEY ALS Platform Trial Executive Committee under Section 12.1, at least forty-five (45) days prior to the submission of the Study Publication. Company and/or Healey Center shall advise the Site within forty-five (45) days of receiving any Study Publication if the Study Publication: (i) contains or discloses any potentially patentable inventions (“Patentable Material”), or (ii) contains any Healey Center or Company Confidential Information. Site will agree to delete any Patentable Material or Confidential Information.

12.3. Use of Company’s Name. Company may request that their name be included or omitted in a Study Publication in accordance with acceptable standards and publication policies.