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Second Amended Protocol for Exploratory Study of Entire-body PET Scans for Multiple Sclerosis (EPSMS)*

Carl Taswell, David Jordan, Dafang Wu, Stephen Lokitz, Harshad Kulkarni, John Prior and the EPSMS Community[†]

Amendment

The Brain Health Alliance Research Protocol BHA-2020-11 for the exploratory study of *Entire-body PET Scans for Multiple Sclerosis* (EPSMS) has previously been published (Taswell 2020), the clinical trial registered at ClinicalTrials.gov as the EPSMS Study NCTO4390009, and a first amendment published (Taswell 2023). This second amendment reports additional changes in the design of the research protocol:

- 1. The inclusion criterion for participants' age from 25 to 55 (Taswell 2020, p.5) will be changed to the range from 25 to 65.
- 2. The radiopharmaceutical Amyvid (F18-florbetapir, Eli Lilly and Company (2025)) for PET-CT imaging scans (Taswell 2020, p.6) is not available for use at some potential collaborating medical imaging centers. Other FDA-approved amyloid imaging agents Neuraceq (F18-florbetaben, Life Molecular Imaging Ltd (2025)) and Vizamyl (F18-flutemetamol, (GE Healthcare Inc 2025)) will be used according to the expertise of the imaging center and availability of the radiopharmaceutical at the location.
- State-of-the-art PET-CT scanners (Taswell 2020, p.6) are not available for use at some potential collaborating medical imaging centers. Other high-resolution PET-MR scanners may instead be available at these locations and will be used according to the expertise of each imaging center.
- 4. When possible at collaborating imaging centers that have both PET-CT and PET-MR scanners, participants will be scanned with both imaging technologies if conducted on the same day for the same radiopharmaceutical dose administered to each participant.

All other aspects of Brain Health Alliance Research Protocol BHA-2020-11 for the EPSMS Study remain as published previously (Taswell 2020; Taswell 2023). None of the changes reported in this amendment increase the risks of side effects, adverse events, or potential harm that may result from participation in this clinical trial. None of the changes reported in this amendment decrease the monitoring of safety for this clinical trial. Prospective participants may inquire about the EPSMS Study at EPSMS.BrainHealthAlliance.net.

Citation

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[†]Correspondence to ctaswell@brainhealthalliance.org.