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

Carl Taswell†

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) and the clinical trial registered at ClinicalTrials.gov as the EPSMS Study NCT04390009. This amendment reports changes in the design of the research protocol:

1. The inclusion criterion for MS patients with advanced state of disease (Taswell 2020, p.5) evidenced by severe disability scores with EDSS ≥ 5.5 (Kurtzke 1983) will not be required.

2. Instead of using the EDSS criterion, research participants will be included in the MS patient group if a credentialed clinical neurologist, who is experienced with the care of MS patients, has diagnosed the patient with MS according to the revised McDonald criteria (Thompson et al. 2018), and shares the medical records documenting the clinical evaluation and diagnosis of the patient.

3. All research participants will be monitored with EDSS score evaluations at the same time as the psychometric evaluations done for each participant in each study group, regardless of whether initially assigned to the patient group (with neurologist reported MS diagnosis and EDSS ≥ 0) or to the normal healthy control group (with EDSS $= 0$ and no prior MS diagnosis) when first enrolled in the EPSMS Study.

4. All research participants who have completed any prior medical imaging scans in the past, including PET scans, MRI scans, and CT scans, may opt-in to providing their medical scans for a retrospective analysis of their old scans and individualized sequential timepoint comparisons (Schork 2022) with their new scans done for the EPSMS Study.

All other aspects of Brain Health Alliance Research Protocol BHA-2020-11 for the EPSMS Study remain as published previously (Taswell 2020). 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.

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†Author affiliated with Brain Health Alliance Virtual Institute, Ladera Ranch, CA 92694 USA; also with University of California San Diego School of Medicine; correspondence to CTaswell at Brain Health Alliance.

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Author: Carl Taswell

Contact: CTaswell at Brain Health Alliance
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