Mount Sinai

Icahn School of Medicine at Mount Sinai
Mount Sinai Beth Israel
Mount Sinai Brooklyn
The Mount Sinai Hospital
Mount Sinai Queens
New York Eye and Ear Infirmary of Mount Sinai
Mount Sinai St. Luke's
Mount Sinai West

**Program for the Protection of Human Subjects**
*Institutional Review Boards*
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# APPROVAL OF RESEARCH

Date: 12/17/2018

To: **Benjamin Natelson, MD (benjamin.natelson@mountsinai.org)**

On **12/14/2018**, an Institutional Review Board of the Mount Sinai School of Medicine, in accordance with Mount Sinai's Federal Wide Assurances (FWA#00005656, FWA#00005651) to the Department of Health and Human Services approved the following human subject research from **12/23/2018** until **12/22/2019** inclusive:

| | |
|---|---|
| Type of Review: | **Continuing Request for Approval** |
| Project Title: | **Multi-Site Clinical Assessment of Chronic Fatigue Syndrome (CFS)** |
| Investigator: | **Benjamin Natelson, MD (Dept: NE - Neurology)** |
| Project Information: | **HS#: 16-01467** |
| Sites: | **Beth Israel** |
| IND or IDE (if any): | **No INDs;No IDEs;** |
| Submission Details (if any): | **Removed personnel: Diana Vu.**<br>**Added personnel: Sarah Khan.** |

Between **11/5/2019** and **11/10/2019**, or within 30 days prior to study close, whichever is earlier, you are to submit a completed FORM HRP-212: Continuing/Final Review Progress Report and required attachments, in order to request continuing IRB approval or study closure. If IRB continuing review approval is not granted before the expiration date of **12/22/2019**, IRB approval of this research expires on that date.

- The IRB has determined that this research involves no greater than MINIMAL RISK. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45CFR.46.102; 21CFR50.3k).
- The IRB approved this research under **expedited review procedure category(ies) 2, 3, 5 and 7**

In conducting this research you are required to follow the requirements listed in the **Investigator Manual**. If stamped approved consent forms are attached, use copies of these forms to document consent. IRB approval does not constitute or imply institutional support for the conduct of this research. Additionally, all required local committee approvals at each **research affiliate** site must be obtained prior to initiation.

cc: Study Contact(s): Sarah Khan (sarah.khan1@mountsinai.org)