Appendix F. Summary of Protocol Changes

On March 6, 2015, our study team submitted an amendment to the IRB proposing to restructure the timeline for study participants. We clarified that the 3-month enrollment period would begin on the date of orientation rather than the date of consent. We made this change to accommodate patients with spaced out clinic schedules. The IRB approved this amendment on March 16, 2015.

We submitted an amendment on March 20, 2015, proposing to add a resource questionnaire that gathered information on emergency department visits outside of MGH. We also added a psych resource questionnaire to inquire about patient's recent mental health services and an ECOG Performance Status questionnaire so that patients could self-report their performance status if it is not listed in their electronic medical record. Lastly, this amendment added a question to the patient qualitative interview to inquire if doctors brought up adherence and symptom reports from the mobile application during clinic visits. This amendment was approved by the IRB on April 14, 2015.

On July 12, 2015, our team submitted an amendment to replace the Memorial Symptom Assessment Scale (MSAS) with the MD Anderson Symptom Inventory (MDASI) to collect participant self-report data at baseline and post-assessment. Due to an administrative error, we had not collected any data using the MSAS or full MDASI at the baseline or post assessments before the submission of this amendment. Participants assigned to the intervention group who utilized the mobile app had been completing an abbreviated MDASI on a weekly basis. This amendment was approved by the IRB on July 30, 2015.

We submitted an amendment on August 14, 2015, proposing to add a pill diary that would be given to all participants when they enrolled in the study. The pill diary was an optional tool, and was not an official measure of adherence. Rather, it was given to participants to use in the case that they had notes they would like to take regarding their adherence on any particular day. This amendment was approved by the IRB on August 26, 2015.

On October 19, 2015, our study team submitted an amendment to add Mass General West (MGH West) as a study site to aid in our enrollment efforts. Additionally, we proposed to change our adherence monitor (GlowCap to MEMS). This amendment was approved by the IRB on November 4, 2015.

On December 2, 2015, we submitted an amendment proposing to add an "app usability questionnaire" to the post-assessment with the intervention group. This questionnaire gathered information about the usability of the app. This amendment was approved by the IRB on December 4, 2015.

We submitted an amendment on March 23, 2016, proposing to increase the overall study accrual from 180 to 200 participants. This amendment was approved on March 29, 2016. On June 3, 2016, we submitted an additional amendment to increase the accrual once again from 200 to 220 participants. This amendment was approved by the IRB on June 20, 2016. By increasing accrual to 220 participants, we were able to enroll more than 180 participants to account for those who dropped out or expired after randomization.