MEMORANDUM

To: William Hundley, M.D.
Int Med-Cardiovascular Med

From: Chair, IRB # 6
Institutional Review Board

Date: 12/1/2015

Subject: Human Protocol: IRB00032416
Community Hospital Identification of High CV Risk Patients during Cancer Treatment (CHI)
Amendment 3 for IRB Study #IRB00032416

Study Documents:
Protocol Version: Appendix 1 ALBUS Data Submission Checklist 04-09-15 wo tracking.docx, Appendix 2 Eligibility Checklist Registration 05-22-15.doc, Appendix 3 Flow Sheet Albus 05-22-15 wo tracking.docx, Appendix 4 MRI Patient Information ALBUS 04-09-15 wo tracking.docx, Appendix 5 Lab Instructions ALBUS 04-09-15 rev 09-11-15 wo tracking.docx, Appendix 6 Early Withdrawal Form ALBUS 04-09-15 wo tracking.docx, Appendix 7 Screening Form ALBUS 04-09-15 wo tracking.docx, Appendix 8 PROMIS Fatigue Short Form 04-09-15 GB wo tracking.docx, Appendix 9 RAND 36 Item Short Form Survey wo tracking.docx, CHI Protocol wo tracking 07 24 15 rev 091115_10.11.15rrHSG.docx, Community Hospital Identification; Informed Consent Version: CHI WF Consent 9 1 15 wo tracking rev 091115_10.11.15_rrHSGfinal.docx (approved), CHI WF Consent 9 1 15 wo tracking rev 091115_10.11.15_rrHSGfinal_12.01.15.docx (approved), Revised Clean Consent 04-09-15 (approved);
Other Documents: Appendix 1 Data Submission, Appendix 10 - Screening Form, Appendix 11 - PROMIS Fatigue Short Form, Appendix 2 Eligibility Checklist, Appendix 3 - Albus Flyer, Appendix 4 - Flow Sheet, Appendix 5 - MRI Patient Information, Appendix 6 - MRI Encounter Form, Appendix 7 - ECHO Encounter Form, Appendix 8 - Lab Instructions, Appendix 9 - Early Withdrawal Form

The Institutional Review Board voted approval of the amendments listed below at its meeting of 12/1/2015. This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

Protocol
2. Brief Eligibility Criteria: “Newly diagnosed” deleted
3. Inclusion Criteria: “Newly diagnosed” deleted; = or > deleted
4. Exclusion Criteria: 4.2.5: “must have been obtained per protocol 98123” added; “10 days prior to registration is required” deleted
5. Agent Administration: “Midazolam” deleted
6. Pharmaceutical Information: “Midazolam” deleted; “Sedative” added; “called midazolam” deleted
7. Agent Accountability: “Midazolam” deleted; “sedative” added

8. 7.1 Schedule of Events: “self-report questionnaires” deleted; “s” deleted from MRIs; “The acquisition of the patient’s……of this measurement is not required” added; “monthly at 2 months and 6 months” deleted; “ultrasensitive Troponin I and Self-Report Questionnaires” added; “At 6 months a Fast MRI……will be obtained” added

9. 7.3 Evaluations During Study Intervention: “monthly” deleted; “at 2 months” added

10. 7.6 Methods for Clinical Procedures: “Albus Imaging” added; “Holly Goodwin” deleted; clinicaltrials@albusimaging.com added; holly@albusimaging.com deleted

11. 7.7 Study Parameters Table: “A portion of the Baseline (98213) MRI……and 6 months” added; “Patients must receive Fast MRI and 3D ECHO……completed prior to start of chemotherapy” deleted; Table updated for clarification; “Patients must receive….prior to first chemotherapy” deleted; “Fast MRI (embedded in Baseline (98213))….prior to first chemotherapy treatment” added; “(B) if applicable anytime during study” added

12. 10.2 Protocol Specific Reporting….: “Hospitalizations that are scheduled…do not need to be reported” added

13. 11.1 Data Management Schedule: updated for clarification

14. 12.3 Analysis Plan: “or larger” deleted; “estimate” deleted

15. 12.5 Power and Sample Size…..: “predictive strength” added

Consent:

1. What are the Study Groups: Diagram updated for clarification

2. What Extra Test….: “& Echocardiogram…..” deleted; “The fast MRI….baseline echocardiogram for this study” added; “monthly” deleted; “at baseline, 2-months and 6 months” added; “add your baseline clinical echocardiogram” added; “for” added; “biomarkers” deleted

3. What Possible Risks….: “called midazolam” deleted; “sedative” added

Appendices:

1. App. 1 Data Submission Checklist: Appendix 4 deleted; addenda added; Fast added; Self-Report Questionnaires added; 1, 3, 4, and 5 Month added

2. App.2 Eligibility Checklist: Updated to match criteria for PREVENT 98213 study

3. App. 4 Flow Sheet: “Put remarks on…..” deleted; “Page #” added. Header on 2nd page updated; extra blank lines added

4. App. 6 MRI Procedure Encounter Form: updated for clarification

5. App. 7 ECHO Encounter Form: updated for clarification

6. App. 8 Lab Instructions: updated for clarification

7. App. 10 Screening Form: “or lymphoma” added

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.

Gregory Hawkins, Ph.D.