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FWA #00002630
IORG #0004299

August 25, 2016

John C Chang, MD
Attn: Alicja M Ball, BS, Jasmine Garrett
Banner MD Anderson Cancer Center
2945 E. Banner Gateway Dr.
Gilbert, AZ 85234

RE: Project # 14-16-0047
A Retrospective Chart and Imaging Review of Patients With Colorectal Cancers Treated at BMDACC
iRIS Reference # 017417
IRB Expedited Approval – New Protocol (Version 1.4 dated 08/04/2016) Data Collection Log (Version 2.0 dated 06/22/2016), Master Log (Version 2.0 dated 06/22/2016), Waiver of Informed Consent and HIPAA Authorization

Dear Dr. Chang:

This letter serves to notify you the above referenced submission received expedited review and approval by Jade Homsi, MD, Chair of the Banner Health Institutional Review Board (Oncology Panel) on August 25, 2016 for conduction at Banner MD Anderson Cancer Center. This expedited review was performed in accordance with 21CFR56.110 (b) and/or 45CFR46.110(b). This study has received approval for one year. Federal regulations require all studies be reviewed at least annually. It was determined all the specified criteria for a waiver of HIPAA Authorization were met. It is recognized the request meets the following requirements for waiver of authorization:

- Use and disclosure involves no more than minimal risk to the patients
- The research could not practicably be conducted without the waiver
- The research could not be conducted without the use of the PHI
- The privacy risks are reasonable in relation to the anticipated benefits

The Board's approval to conduct your study will expire on **August 25, 2017**. The IRB requests that you submit a Continuing Review report one month prior to the **July 2017** IRB meeting. This allows time for processing and review prior to the IRB expiration date of the study.

Any internal unanticipated problems or unexpected drug/biologic adverse events must be reported to the IRB within 7 working days of the investigator learning of the event.

If you wish to change any aspect of this study, such as the procedures or the investigators, please communicate your requested changes to the Board. The new procedure is not to be initiated until the IRB approval has been given.

Unusual events, results of the study or any additional information relative to the study must be submitted to the Board. A Closing report is required upon completion of the project. In the event the study results are published, please send a copy to the Banner Research so it may be included in the file. A copy of this letter will be retained electronically.

The Board appreciates your participation in research. If you have any questions, please contact Cindy Soto, Research Regulatory Specialist, at 480.412.3935.

Sincerely,

Signature applied by Jade Homsi on 08/25/2016 11:22:22 AM MST

Jade Homsi, MD
Chair, Banner Health IRB (Oncology Panel)

JH/cs
cc: Research Director