



RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-7091

6/19/2015

Sarah Hoffe, M.D.
H Lee Moffitt Cancer Center
12902 Magnolia Drive
Tampa, FL 33612

RE: **Expedited Approval for Continuing Review**

IRB#: CR4_Pro00003382

Title: Retrospective analysis of all patients with gastrointestinal malignancies (primary and metastatic) treated with external beam radiation, brachytherapy, or radioembolization at MCC

Study Approval Period: 7/15/2015 to 7/15/2016

Dear Dr. Hoffe:

On 6/17/2015, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents outlined below.

Approved Item(s):

Protocol Document(s):

[16567 RA GI-RT Protocol Vers6 10-02-2014](#)

The waiver of informed consent process and the waiver of HIPAA authorization have been renewed.

The IRB determined that your study qualified for expedited review based on federal expedited category number(s):

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

A handwritten signature in blue ink that reads "Vjorgensen MD". The signature is written in a cursive style with a large initial "V".

E. Verena Jorgensen, M.D., Chairperson
USF Institutional Review Board