OMB#: 0925 – 0625 Expiry Date: 01/31/2014

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of your participation in the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) Initiative is protected by The Privacy Act of 1974, as amended. The purpose of the information collection is to conduct reviews of clinical trial studies. Although your participation in NCI-sponsored research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0625). Do not return the completed form to this address.

Study Review Responsibility Transfer Form

Submission of this Study Review Responsibility Transfer Form indicates that the CIRB is no longer the IRB responsible for review of this study. This is a two-step process. Step 1 is to complete this form. Step 2 is to confirm the information and submit.

Step 1: Complete this form.

A: Click "Next" once the form is completed and you will be taken to the confirmation page.

Note: If you wish to transfer more than one study, a separate request must be made for each study being transferred.

Fields marked with * are required.

*Study Number: Select from the List

Study Title:

*Name of Local IRB: Select from the List

*Institution's FWA Number Auto-populate

*Local IRB Registration Number Auto-populate

☐ Click this box if there are study participants enrolled at a site covered by this IRB. If so, upload a copy of the IRB approval letter. NOTE: Your IRB must have approved the study via local procedures before transfer so there is no lapse in IRB oversight of the study.

*Upload IRB Approval Letter:

☐ Click this box if there are no study participants enrolled at a site covered by this IRB. NOTE: Proof that the study is open is not required since there are no participants enrolled.

If you have any questions, call the NCI CIRB Helpdesk at 888-657-3711 or email

ncicirbcontact@emmes.com.

NEXT BUTTON

If you wish to return to the Facilitated Review Submission Report, click the ‘Go Back” button (all information entered will be lost). GO BACK BUTTON

Step 2 – Confirmation and Submission

Step 2: Review information on this confirmation page and click "Submit" if information is correct. If changes are required, click "Go Back" and you will be returned to the Study Review Responsibility Transfer Form where you may make changes.

A: Once you click "Submit", your browser will automatically take you back to the Facilitated Review (FR) Submission Report webpage.

B: You will receive an email from the CIRB Operations Office confirming receipt of your transfer request.

Study Number: CALGB-80303

Study Title: "A Randomized Phase III Trial of Gemcitabine Plus Bevacizumab (NSC #704865 IND# 7921) versus Gemcitabine Plus Placebo in Patients with Advanced Pancreatic Cancer"

Name of IRB: Missouri Baptist Medical Center

Institution's FWA Number: FWA00001234

Local IRB Registration Number: IRB00001234

Study participants are enrolled at a site covered by this IRB.
OR
Study participants are not enrolled at a site covered by this IRB.

IRB Approval Letter, if applicable: C:\Documents and Settings\lcovington\Desktop\ transcript.doc OR Not applicable

After your review, select the appropriate option below:

If you want to change any information, click on "Go Back". ['Go Back' Button]
OR

If the information is correct, click the Submit button. You will receive an email acknowledgement of the submission.
['Submit' Button]